COPY-
Application

Medical Care, PLLC

CN1303-006

nelley & company pllc

2013 MAR 13 AM 8 49

Rachel C. Nelley, Attorney
rachel@nelleycompany.com
615.274.4838

March 13, 2013

VIA HAND DELIVERY

Ms. Melanie M. Hill
Executive Director
Health Services & Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, TN 37243

Re: Certificate of Need Application
Medical Care, PLLC

Dear Ms. Hill:

Enclosed for filing with your office please find the original and two (2) copies of the certificate of need application of my client, Medical Care, PLLC, along with a check in the amount of $3,000.00 for the requisite filing fee.

Should you have any questions or require additional information pertaining to this application, please do not hesitate to contact me by telephone at 615.274.4838 or by e-mail at rachel@nelleycompany.com.

Very truly yours,

Rachel C. Nelley
Attorney

Attachments
cc: Steve Hopland, Medical Care, PLLC

1. ***Name of Facility, Agency, or Institution***

2013 MAR 13 AM 8 49

Medical Care, PLLC
Name

1500 West Elk Avenue
Street or Route

Carter
County

Elizabethton
City

TN
State

37643
Zip Code

2. ***Contact Person Available for Responses to Questions***

Rachel C. Nelley
Name

Attorney
Title

Nelley & Company, PLLC
Company Name

rachel@nelleycompany.com
Email address

PO Box 150731
Street or Route

Nashville
City

TN
State

37215
Zip Code

Attorney
Association with Owner

(615)274-4838
Phone Number

(615)730-6545
Fax Number

3. ***Owner of the Facility, Agency or Institution***

Medical Care, PLLC
Name

(423)431-0527
Phone Number

1500 West Elk Avenue
Street or Route

Carter
County

Elizabethton
City

TN
State

37643
Zip Code

4. ***Type of Ownership of Control (Check One)***

A. Sole Proprietorship
B. Partnership
C. Limited Partnership
D. Corporation (For Profit)
E. Corporation (Not-for-Profit)
F. Government (State of TN or Political Subdivision)
G. Joint Venture
H. Limited Liability Company
I. Other (Specify) PLLC

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. ***Name of Management/Operating Entity (If Applicable)***

Pine Palms Management, LLC
Name

401 E. Main Street
Street or Route

County

Johnson City
City

TN
State

37601
Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. ***Legal Interest in the Site of the Institution (Check One)***

A.	Ownership		D.	Option to Lease	
B.	Option to Purchase		E.	Other (Specify)	
C.	Lease of 5 Years	X			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

7. ***Type of Institution (Check as appropriate--more than one response may apply)***

A.	Hospital (Specify)		I.	Nursing Home	
B.	Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty		J.	Outpatient Diagnostic Center	
			K.	Recuperation Center	
C.	ASTC, Single Specialty		L.	Rehabilitation Facility	
D.	Home Health Agency		M.	Residential Hospice	
E.	Hospice		N.	Non-Residential Methadone Facility	
F.	Mental Health Hospital				
G.	Mental Health Residential Treatment Facility		O.	Birthing Center	
			P.	Other Outpatient Facility (Specify)	
H.	Mental Retardation Institutional Habilitation Facility (ICF/MR)		Q.	Other (Specify) Physician Office	X

8. **Purpose of Review *(Check) as appropriate--more than one response may apply)***

A.	New Institution		G.	Change in Bed Complement *[Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation]*	
B.	Replacement/Existing Facility				
C.	Modification/Existing Facility				
D.	Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) MRI	X	H.	Change of Location	
			I.	Other (Specify)	
E.	Discontinuance of OB Services				
F.	Acquisition of Equipment				

9. Bed Complement Data

Please indicate current and proposed distribution and certification of facility beds.

		Current Beds Licensed	*Current Beds *CON*	*Staffed Beds*	*Beds Proposed*	*TOTAL Beds at Completion*
A.	Medical					
B.	Surgical					
C.	Long-Term Care Hospital					
D.	Obstetrical					
E.	ICU/CCU					
F.	Neonatal					
G.	Pediatric					
H.	Adult Psychiatric					
I.	Geriatric Psychiatric					
J.	Child/Adolescent Psychiatric					
K.	Rehabilitation					
L.	Nursing Facility (non-Medicaid Certified)					
M.	Nursing Facility Level 1 (Medicaid only)					
N.	Nursing Facility Level 2 (Medicare only)					
O.	Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P.	ICF/MR					
Q.	Adult Chemical Dependency					
R.	Child and Adolescent Chemical Dependency					
S.	Swing Beds					
T.	Mental Health Residential Treatment					
U.	Residential Hospice					
	TOTAL					

*CON-Beds approved but not yet in service

10. Medicare Provider Number 3373580

Certification Type Physician Group Practice

11. Medicaid Provider Number 1512986

Certification Type Physician Group Practice

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid?

13. *Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.* Will this project involve the treatment of TennCare participants? Yes **If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted *or plans to contract.***

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

SECTION B: PROJECT DESCRIPTION

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Medical Care, PLLC (the "Applicant") seeks a certificate of need to acquire a GE Signa Excite 1.5 Tesla stationary magnetic resonance imaging ("MRI") scanner system and initiate MRI services to its patients. In 2011, Medical Care, PLLC saw a total of 23,483 patients. 10,754 (45.79%) of the patients resided in Carter County. 8,856 (37.71%) of the patients resided in Washington County. 1,333 (5.68%) of the patients resided in Sullivan County. 911 (3.88%) of the patients resided in Johnson County. 771 (3.28%) of the patients resided in Unicoi County. 858 (3.65%) of the patients resided outside the proposed service area. Accordingly, the proposed service area is comprised of Carter, Washington, Sullivan, Johnson and Unicoi Counties in Tennessee. With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration.

Medical Care, PLLC, a NCQA[1] certified level 3 Patient Centered Medical Home[2], is a multi-specialty medical practice with 17 physicians and 14 physician extenders in specialties that include family practice, general practice, internal medicine, general surgery, gynecology and pediatrics with office locations in Elizabethton, Hampton and Johnson City, in Tennessee. The proposed MRI will be located at the Elizabethton office, which is conveniently located on Highway 67 across the street from Sycamore Shoals Hospital at 1500 West Elk Avenue in Elizabethton, Carter County, Tennessee, and will occupy 674 square feet of space (currently being used for storage) in the medical practice's existing radiology department. The space for the MRI will be leased from Pine Palms Management, LLC.

Medical Care, PLLC is a family owned professional limited liability company whose members are Arnold Hopland, MD (33.33%), Jeffrey Hopland, MD (33.33%), and Kenneth Hopland, MD (33.33%). The physician owners are all duly licensed in Tennessee and practice at Medical Care, PLLC.

Pine Palms Management, LLC (formerly known as Medical Care, LLC), which owns all of the assets utilized by the medical practice of Medical Care, PLLC, including real estate and equipment, is also a closely held family business. Its owners are Dr. Arnold Hopland, MD

---

[1] National Committee for Quality Assurance ("NCQA") is a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups. In Tennessee, all plans contracting with TennCare (Medicaid) must be NCQA Accredited.

[2] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

(20%), Steven Hopland (20%), Jeffrey Hopland, MD (20%), Jennifer Whaley (20%) and Kenny Hopland, MD (20%).

Pine Palms Management, LLC owns the 120,000 square foot building located at 1500 West Elk Avenue in which the proposed MRI will be housed. Medical Care, PLLC occupies approximately 45,000 square feet of space in the building. The remaining 48,700 square feet of office space in the building is or will be leased to other businesses primarily in the medical services industry. Current tenants include Amedysis home health, Amedysis hospice care, Physical Therapy Services, and Wellmont CVA Heart Institute. Future tenants evidenced by letters of intent include Aeroflow (a DME company), Solstas Lab Services, a sleep lab as well as practices specializing in allergy and asthma, neurology, and pulmonology. The building includes a 22,000 square foot parking garage.

During the first year of operation, Medical Care, PLLC estimates that it will perform 2,756 MRI scans. Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annual growth of 5-10%. Its MRI utilization projections for each year following its initial year in operation assume a conservative 5% growth.

In 2011, the average utilization of providers in all the counties comprising the Applicant's service area excluding Johnson County, which has only a mobile scanner that operates 2 days per month, was 2208. Excluding private physician offices and a standup MRI, the 2011 average utilization of providers in this area (Carter, Washington, Sullivan, and Unicoi counties) was 2725.

The Applicant's patients experience many days' waiting time for scheduled MRI service, particularly in Carter County where 45.79% of its patients reside. Per current policy at Sycamore Shoals Hospital, the sole existing MRI provider in Carter County, and other Mountain States Health Alliance owned facilities, in order to "allow ample time for [its] patients to secure financial clearance," non-emergent cases must be scheduled at least three (3) business days in advance of the scan. See letter from Mountain States Health Alliance included as Attachment B.I. For non emergency MRI studies, Medical Care, PLLC providers have seen their patients have to wait several weeks to be scheduled locally or have to drive to a facility outside the county in order to have the MRI scheduled sooner. These waits underscore the need to add capacity in the community.

Approval of the project would result in patients experiencing shorter wait time and improved convenience. The ability of the practice to control exam scheduling and results reporting will expedite the diagnosis and treatment of Medical Care, PLLC patients, thereby improving patient outcomes.

The current outpatient MRI market in the Applicant's service area is strongly dominated by Mountain States Health Alliance ("MSHA"), which owns Sycamore Shoals Hospital in Carter County (the sole MRI provider in Carter County), all MRI units available to outside patients in Washington County (Johnson City Medical Center in Washington County, Franklin Woods Community Hospital in Washington County and Mountain States Imaging at Med Tech Parkway in Washington County), is the sole MRI provider in Johnson County (Johnson County

Community Hospital – mobile unit operating only 2 days per month), and owns Indian Path Medical Center in Sullivan County. MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility at the sole MRI provider in Unicoi County. No viable competitors exist in Carter, Johnson, Washington and Unicoi Counties. 90.66% of the Applicant's patients reside in these counties.

The lack of competition in the service area has reduced access, increased costs and not encouraged efficiencies. The market dominance of Mountain States Health Alliance in the Applicant's service area has generated an access issue for patients of Medical Care, PLLC not solely related to scheduling delays. Mountain States Health Alliance recently implemented an up-front 50% payment requirement for any nonemergency imaging procedure and has been unwilling to make payment options available for the initial 50% prior to scheduling tests such as MRI. See letter from Mountain States Health Alliance included as Attachment B.I. In 2011, the average charge per MRI scan in Carter County was $3,776.74 (in 2010, it was $3,483.01). The 50% up-front payment requirement imposed by Mountain States Health Alliance limits access to MRI services not only for cash paying or uninsured patients, but patients with fixed incomes or with high deductible health plans. Medical Care, PLLC has seen multiple patients choose to forego recommended diagnostic imaging due to the large up-front payment requirement imposed by Mountain States Health Alliance. Additionally, Mountain States Health Alliance has elected not to be in network with CIGNA insurance company, a plan offered by several large employers in the area. Employees with CIGNA insurance must travel outside the Mountain States Health Alliance service area to obtain in-network diagnostic tests. Approximately 15% of the Medical Care, PLLC patients with private insurance have Cigna.

Competitors of Mountain States Health Alliance exist in Sullivan County, but only 5.68% of the Applicant's patients reside in Sullivan County and all but one (1) of the MRI providers available to the Applicant's patients are operating at or above capacity -- Bristol Regional Medical Center's scanners each averaged 3223.5 scans in 2011; Holston Valley Medical Center's scanner averaged 3774 scans in 2011; Holston Valley Imaging Center saw 8362 scans (2787.3 per scanner) in 2011; Meadowview Outpatient Diagnostic Center experienced 4457 scans in 2011 (5258 in 2010) using 1 fixed scanner; Sapling Grove Outpatient Diagnostic Center saw 2587 scans in 2011. Volunteer Parkway Imaging Center, located in Bristol, Tennessee, experienced 1327 scans in 2011, but, in order to access this scanner, patients of Medical Care, PLLC would have to travel 21 miles (about a 35 minute drive) from Elizabethton. The only other option would be to travel 21 miles to Erwin, Tennessee to Unicoi County Memorial Hospital (whose MRI utilization in 2011 was 1630 in 2011) for a scan. Only 3.28% of the Applicant's patients reside in Unicoi County. Further, as mentioned above, MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility.

The total cost of the project is estimated to be $838,543. This includes the purchase and installation of the GE Signa Excite 1.5 Tesla stationary MRI scanner system, RF shielding, computers, cosmetic finishing of the space, a new HVAC system and additional electrical service and furnishings.

Financing for the project will be accomplished with cash reserves and a bank loan.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and /or renovation of the facility (exclusive of major medical equipment covered by T.C.A. 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Please also discuss and justify the cost per square foot for this project.

This project does not involve construction costs in excess of $2 million and is not a hospital project. Rather, it involves the renovation of approximately 674 square feet of leased space located on the first floor of the medical office building housing the Elizabethton location of the medical practice of Medical Care, PLLC (which occupies 45,000 sq. ft. of space) located at 1500 West Elk Avenue in Elizabethton, Tennessee. Medical Care, PLLC proposes to convert existing storage space into an MRI suite. An existing exterior doorway will be removed during construction to allow for installation of the MRI magnet and equipment. An RF shield will be assembled by National MRI Shielding within the existing 25.5' by 17.5' existing room. The electrical contractor will add 3 phase 480 volt electric supply from the adjacent electrical room and coordinate the connection to MRI power supply with the MRI equipment installer. The electrician will also install an MRI approved nonmetallic lighting system. The HVAC contractor will install a new HVAC system as recommended by the MRI manufacturer to adequately control the temperature in the MRI suite. The general contractor will install, finish & paint drywall inside the RF shielded room along with drop ceiling and trim. The total estimated construction cost to modify the existing 674 square feet is $80,220. This is a construction cost of $119 per square foot. This entire cost is associated with modification / renovation of existing space.

The proposed MRI suite will include: a 446 square foot RF shielded MRI magnet room, a 140 square foot MRI mechanical equipment room, and an 88 square foot MRI tech/operator room. The existing adjacent radiology department includes a separate exterior entrance, patient bathroom, reception area for patient check in/out, patient waiting area, patient changing rooms, and imaging modality rooms for x-ray, CT, mammography, ultrasound, and nuclear medicine. The total radiology department including the proposed MRI is 4,300 SF.

The cost for the cosmetic finishing of the space for the project is projected by the contractor to be $5,000. The cost for electrical service and lighting will have an estimated cost of $15,000. The applicant will acquire some furniture and office equipment at an approximate cost of $3,000. The new HVAC system and electrical service will cost $20,000. RF shielding enclosure of the MRI room is expected to cost $30,220. The total cost per square foot is $119 per square foot.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and or redistributed by this application.
Not applicable

C. As the Applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. **Magnetic Resonance Imaging (MRI)**
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

Medical Care, PLLC proposes to initiate magnetic resonance imaging (MRI) services using a GE Signa Excite 1.5 Tesla magnetic resonance imaging ("MRI") scanner with short bore magnet for patients of the medical practice.

Current MRI utilization
Historically, the physicians at Medical Care, PLLC directly order an average of 80 MRI studies per/month (960 MRI studies annually) through the practice's electronic medical record (EMR) system. Additionally, the practice estimates that 24 MRI studies per month (288 MRI studies annually) are directly ordered by the physicians at Medical Care, PLLC but are not captured by the EMR system as they are hand written orders or telephone referrals to MRI providers.

Internal direct ordered MRI = 960 + 288 = 1248

Medical Care, PLLC also refers patients to neurology / neuroscience specialists for MRIs. If the project is approved, these MRIs would be performed at the medical practice. One of these providers, Northeast Tennessee Associate Neurology, estimates that it receives 50 patient referrals from Medical Care, PLLC per month (600 MRI patients annually) who require MRI

studies. One other provider, East Tennessee Brain & Spine, estimates that it receives 15-20 patient referrals from Medical Care, PLLC per month (180-240 MRI patients annually -- average 210). Medical Care, PLLC estimates that it refers an additional 16 patients per month (192 annually) to other neurologists for MRI studies.

neurology / neuroscience patient MRI = 600 + 210 + 192 = 1002 studies

In addition, Medical Care, PLLC refers between 75-100 patients per month (or 88 patients on average) to orthopedic specialists. The practice estimates that 40% of these patients will require an MRI for evaluation. Of these patients who require an MRI, the practice estimates that 20% will require an additional MRI post treatment within a year. If this project is approved, Medical Care, PLLC will perform these additional MRI studies on site at the medical practice.

Initial 88pts/mo x 12mo x 40% = 422 initial MRI
422 initial MRI x 20% = 84 repeat MRI
Total orthopedic referral MRI = 506 studies

Total estimated MRI all sources (1,248 + 1,002 + 506) = 2,756

Future MRI utilization
Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annually growth of 5-10%. The MRI will grow consistently with the group and patient volumes.

1st Year estimated MRI studies	*2,756*
2nd year estimated MRI studies (+5% growth)	*2,894*
3rd year estimated MRI studies (+5% growth)	*3,038*
4th year estimated MRI studies (+5% growth)	*3,190*
5th year estimated MRI studies (+5% growth)	*3,350*

Timely scheduling of MRI scans for the Applicant's patients is an issue. The Applicant's patients experience many days' waiting time for scheduled MRI service, particularly in Carter County where 45.79% of its patients reside. Per current policy at Sycamore Shoals Hospital, the sole existing MRI provider in Carter County, and other Mountain States Health Alliance owned facilities, in order to "allow ample time for patients to secure financial clearance," non-emergent cases must be scheduled at least three (3) business days in advance of the scan. See letter from Mountain States Health Alliance included as Attachment B.I. For non emergency MRI studies, Medical Care, PLLC providers have seen their patients have to wait several weeks to be scheduled locally or have to drive to a facility outside the county in order to have the MRI scheduled sooner. Unfortunately, patients are confronted with the Mountain States Health Alliance scheduling policy at most facilities in surrounding counties as well.

Mountain States Health Alliance ("MSHA") owns Sycamore Shoals Hospital in Carter County (the sole MRI provider in Carter County), all MRI units available to outside patients in Washington County (Johnson City Medical Center in Washington County, Franklin Woods Community Hospital in Washington County and Mountain States Imaging at Med Tech Parkway in Washington County), the sole MRI provider in Johnson County (Johnson County Community Hospital – mobile unit operating only 2 days per month), and Indian Path Medical Center in

Sullivan County. MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility at the sole MRI provider in Unicoi County. No viable competitors exist in Carter, Johnson, Washington and Unicoi Counties. 90.66% of the Applicant's patients reside in these counties.

Mountain States Health Alliance recently implemented an up-front 50% payment requirement for any nonemergency imaging procedure and has been unwilling to make payment options available for the initial 50% prior to scheduling tests such as MRI. See letter from Mountain States Health Alliance included as Attachment B.I. In 2011, the average charge per MRI scan in Carter County was $3,776.74 (in 2010, it was $3,483.01).

The table below represents the average gross charge in 2011 of all MRI providers in the Applicant's service area. Note the substantial (92%) rate increase faced by patients at Mountain States Health Alliance facilities compared to facilities not owned by Mountain States Health Alliance.

County	Facility	Average Gross Charge in 2011
Carter	Sycamore Shoals Hospital*	$3,776.74*
Johnson	Johnson County Community Hospital*	$3,629.35*
Sullivan	Appalachian Orthopaedic Associates – Kingsport	$1,164.61
Sullivan	Appalachian Orthopaedic Associates, PC	$1,064.63
Sullivan	Bristol Regional Medical Center	$2,332.97
Sullivan	Holston Valley Imaging Center, LLC	$2,553.22
Sullivan	Holston Valley Medical Center	$2,125.44
Sullivan	Indian Path Medical Center*	$3,849.93*
Sullivan	Meadowview Outpatient Diagnostic Center	$1,701.49
Sullivan	Sapling Grove Imaging, LLC (Wellmont)	$2,598.00
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,671.94
Sullivan	Volunteer Parkway Imaging Center	$2,365.84
Unicoi	Unicoi County Memorial Hospital	$2,726.90
Washington	Appalachian Orthopaedic Associates – Johnson City	$1,063.86
Washington	Franklin Woods Community Hospital*	$3,810.86*
Washington	Johnson City Medical Center*	$3,853.59*
Washington	Mountain States Imaging at Med Tech Parkway*	$3,718.22*
Washington	Watauga Orthopaedics, PLC	$1,410.16
AVERAGE GROSS CHARGE PER PROCEDURE – ALL facilities		$2,700.78
AVERAGE GROSS CHARGE PER PROCEDURE – owned by Mountain States Health Alliance		$3,773.12
AVERAGE GROSS CHARGE PER PROCEDURE – NOT owned by Mountain States Health Alliance		$1,959.99
% increase in average gross charge		92.51%
**and shading indicates ownership by Mountain States Health Allicance*		

The 50% up-front payment requirement imposed by Mountain States Health Alliance limits access to MRI services not only for cash paying or uninsured patients, but patients with fixed incomes or with high deductible health plans. Medical Care, PLLC has seen multiple patients

choose to forego recommended diagnostic imaging due to the large up-front payment requirement imposed by Mountain States Health Alliance.

Additionally, Mountain States Health Alliance has elected not to be in network with CIGNA insurance company, a plan offered by several large employers in the area. Employees with CIGNA insurance must travel outside the Mountain States Health Alliance service area to obtain in-network diagnostic tests. Approximately 15% of the Medical Care, PLLC patients with private insurance have Cigna.

Competitors of Mountain States Health Alliance exist in Sullivan County, but only 5.68% of the Applicant's patients reside in Sullivan County and all but one (1) of the MRI providers available to the Applicant's patients are operating at or above capacity -- Bristol Regional Medical Center's scanners each averaged 3223.5 scans in 2011; Holston Valley Medical Center's scanner averaged 3774 scans in 2011; Holston Valley Imaging Center saw 8362 scans (2787.3 per scanner) in 2011; Meadowview Outpatient Diagnostic Center experienced 4457 scans in 2011 (5258 in 2010) using 1 fixed scanner; Sapling Grove Outpatient Diagnostic Center saw 2587 scans in 2011. Volunteer Parkway Imaging Center, located in Bristol, Tennessee, experienced 1327 scans in 2011, but, in order to access this scanner, patients of Medical Care, PLLC would have to travel 21 miles (about a 35 minute drive) from Elizabethton. The only other option would be to travel 21 miles to Erwin, Tennessee to Unicoi County Memorial Hospital (whose MRI utilization in 2011 was 1630 in 2011) for a scan. Only 3.28% of the Applicant's patients reside in Unicoi County. Further, as mentioned above, MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility.

Making MRI scans available to patients who would otherwise forego the diagnostic procedure and on a more timely basis to patients who would otherwise have to wait days or weeks to obtain a scan improves patient outcomes in both surgical and non surgical cases thereby complementing the medical services currently being provided by the physicians of Medical Care, PLLC and other providers within the community. Offering MRI scans at the same site where other diagnostic modalities are available to Medical Care, PLLC providers for their patients, including x-ray, ultrasound, nuclear medicine, bone densitometry (DXA), mammography and computed tomography (CT), allows for comprehensive coordinated results, control of patient quality of care and service and direct control over cost.

Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program. Qualuable Medical Professionals has a triple aim to reform healthcare, namely, to improve service, to improve quality, and to lower costs. The ability to offer MRI services at a site adjacent to Medical Care, PLLC will further all three of these goals by improving coordination of care and quality of outcomes at controlled costs.

Medical Care, PLLC is a NCQA[3] certified level 3 Patient Centered Medical Home[4]. In order to obtain this level of certification, the practice achieved the highest level of coordinated proactive patient centered care after being evaluated both onsite and offsite according to NCQA standards, known throughout the healthcare industry as being the most rigorous in evaluating quality of care. Medical Care, PLLC is working closely with several of its primary payers in a partnership to improve patient care (quality) and also to reduce costs. Medical Care, PLLC has increased quality measures significantly by improving patient access including diagnostic testing. For example, traditionally primary care physician offices have a difficult time getting diabetic patients to get an annual diabetic eye exam. There have been many barriers to getting this important, yet underutilized diagnostic test. One barrier was the patient financial impact. Many patients and local optometrists were unaware that the patient's medical benefits would pay for routine diabetic eye exams (different from glasses exam). Other barriers include scheduling and convenience, and poor coordination with local optometrists and ophthalmologists. Medical Care, PLLC has implemented a digital fundus camera and diagnostic system into its offices and is now doing routine diabetic eye exam screening. This change in process has significantly increased patient compliance and in the past year has found three significant previously undetected problems and potentially saved the sight of three patients. This is just one example of how better access along with improved processes and coordination of care can significantly impact patient outcomes and long term cost. Similarly, MRI which is convenient and cost effective can give the providers at Medical Care, PLLC the information they need to treat patients in timely and accurate way. The increase in coordination with specialists translates into reduced patient waiting (which is significant when the patient is suffering in pain, both mental and physical) for proper treatment. Sooner interventions can also reduce severity of illness or disease / injury process.

Medical Care, PLLC is also a participant in One Partner Health Information Exchange (HIE) a program in which Mountain States Health Alliance currently does not participate. One Partner, the local HIE, is designed to share medical information between physicians to improve care and reduce duplication of services. One Partner has over 600 healthcare providers contracted to share patient data. This coordination and collaboration is critical for the future of healthcare. The Applicant will be sharing all patient data associated with imaging studies through One Partner. This improved access to other primary care physicians and specialists is necessary for the continued goal of improved care and decreased costs.

D. Describe the need to change location or replace existing facility. *Not applicable.*

E. Describe the acquisition of any item of major medical equipment (as defined by agency rules and the statute) which exceeds cost of $1.5million; and/or is a magnetic

---

[3] National Committee for Quality Assurance ("NCQA") is a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups. In Tennessee, all plans contracting with TennCare (Medicaid) must be NCQA Accredited.

[4] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. **For fixed- site major medical equipment (not replacing existing equipment):**

   a. Describe the new equipment, including:

   1. **Total cost (as defined by Agency Rule);**
   2. **Expected useful life;**
   3. **List of clinical applications to be provided;**
   4. **Documentation of FDA approval.**

   The Applicant proposes to initiate magnetic resonance imaging (MRI) services using a reconditioned GE Signa Excite 1.5 Tesla MRI scanner with short bore magnet. A proposal from Oxford Instruments Service, LLC for purchase of the equipment at a cost of $426,984 [(MRI) $399,000+(Tax) $27,984]is attached as Attachment B.II.E.1.a.1. The expected useful life of the machine is 15 years. Since the machine which the Applicant plans to purchase is 8 years old and has been reconditioned it is expected it will have at least another 7+ years of operation. The GE 1.5 Tesla magnet is currently factory upgradeable to equivalent new GE 1.5 Tesla magnets through upgraded software and computers. A list of clinical applications to be provided is included as Attachment B.II.E.1.a.3. Documentation of FDA approval is included as Attachment B.II.E.1.a.4.

   b. Provide Current and proposed schedules of operations.

   Hours of operation will be 7am until 7pm Monday thru Friday and Saturday 9am until 5pm. The Applicant also plans to be open on all holidays except New Years Day, Memorial Day, Labor Day, 4th July, Thanksgiving Day and Christmas Day.

2. **For mobile major medical equipment:** *Not applicable.*

3. **Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.**

The Applicant intends to purchase GE Signa Excite 1.5 Tesla MRI scanner with short bore magnet for $399,000.00 from Oxford Instruments Service, LLC. The proposal is included as Attachment B.II.E.1.a.1.

III. (A) Attach a copy of the plot plan of the site on an 8 ½" x 11" sheet of white paper which must include:

1. **Size of site (in acres);**
2. **Location of structure on the site; and**
3. **Location of the proposed construction.**

4. **Names of streets, roads or highways that cross or border the site.**

A copy of the plot plan of the site is included as Attachment B.III.(A).

(B) 1.Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

The proposed site of the MRI is 1500 West Elk Avenue, a 4 lane highway also known as Hwy 67 and Hwy 321 that is readily accessible to patients in or traveling to the Elizabethton area. It will be housed within the existing medical practice of Medical Care, PLLC, accessed historically by an average 1,155 patients per month (13,862 annually). West Elk Avenue is the busiest road in Carter County. The building at which the imaging services will be offered has 2 curb cuts directly onto Elk Avenue, along with frontage road from Williams Avenue, where TDOT is currently installing a new traffic light to facilitate better traffic flow. This intersection is also the entrance for Sycamore Shoals Hospital. The Applicant also has rear access to Valley Street and connects to the adjacent shopping center and Hudson Drive.

From Johnson City / Washington County, patients can travel on Hwy 67 (6-7miles) and see the office on the right. From Unicoi County, patients can travel Hwy 26 north to exit 24 right onto Hwy 67and then find the office on right. From Bristol / Sullivan County, patients can travel 19E south toward Elizabethton, turn right on Hwy 67, and see the office on the left. From Kingsport / Sullivan County, patients can travel Hwy 26 South to exit 24, turn left on Hwy 67, and find the office on the right.

Elizabethton does not have a public transportation system. Medical Care, PLLC does have regular patient access by TennCare vans & occasional school buses for team sports physicals.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

Please see Attachment B.IV.

V. For a Home Health Agency or Hospice, identify: *Not applicable.*

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

1. **Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.**

Please discuss how the proposed project will relate to the 5 Principals for Achieving Better Health found in the State Health Plan." Please type out each principal and provide a separate response to each one.

1 The Purpose of the State Health Plan is to improve the Health of Tennesseans.

The availability of an alternative MRI provider in Carter County will increase patient access to important diagnostic equipment not readily available to all Carter County and surrounding area patients. Better access and coordinated patient care will improve patient health outcomes. Patients diagnosed sooner can receive faster treatment resulting in better outcomes at lower overall costs.

In Carter County, Tennessee, where the Applicant's proposed MRI will be located, there is currently only one (1) provider offering MRI services, namely, Sycamore Shoals Hospital. According to the 2012 individual facility Joint Annual Report submitted by Sycamore Shoals Hospital, which reflects a reporting period of July 1, 2011 through June 30, 2012, the hospital performed a total of 2,011 MRI scans (142 inpatient plus 1869 outpatient scans). However, according to the 2011 summary Joint Annual Report of Hospitals, only 35.7% of Carter County residents obtained care in Carter county (i.e., at Sycamore Shoals Hospital). 59.5%, the vast majority of Carter County residents, sought care in neighboring Washington County. Mountain States Health Alliance opened Franklin Woods Community Hospital in Washington County in 2010. That same year, Franklin Woods Community Hospital initiated MRI services using a wide-bore 3T scanner. In 2011, MRI utilization at Franklin Woods Community Hospital increased at a rate of 116.88% from 1635 (in 2010) to 3546, according to the trends noted in the provider medical equipment report/registry maintained by the HSDA dated 10/3/2012. Notably, utilization at Sycamore Shoals Hospital decreased from 2526 in 2008 to 1958 in 2011 reflecting a percentage rate of decrease of 22.5 %. Although the price tag is substantially higher to purchase a 3T (at Franklin Woods Community Hospital) compared to a 1.5T (in use at Sycamore Shoals Hospital, the federal reimbursement does not change (though the gross charge per scan at Franklin Woods of $3527 per scan in 2010 and $3811 per scan in 2011 is substantially higher than the average gross charge per scan of $1,959.99 by other area providers not owned by Mountain States Health Alliance. Accordingly, owners of a 3T MRI have an incentive to increase utilization for the newly purchased 3T MRI and decrease utilization for a 1.5 MRI purchased, particularly if the owner can increase its gross charges for a 1.5T scan at a rate of 41.25% from $2,674 in 2009 to $3,777 in 2011, as at Sycamore Shoals Hospital.

Mountain States Health Alliance owns all MRI units available to outside patients in Washington County (Johnson City Medical Center in Washington County, Franklin Woods Community Hospital in Washington County and Mountain States Imaging at Med Tech Parkway in Washington County), is the sole MRI provider in Johnson County (Johnson County Community Hospital – mobile unit operating only 2 days per month), and owns Indian Path Medical Center in Sullivan County. MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility at the sole MRI provider in Unicoi County. No viable competitors exist in Carter, Johnson, Washington and Unicoi Counties. 90.66% of the Applicant's patients reside in these counties.

Competitors of Mountain States Health Alliance exist in Sullivan County, but only 5.68% of the Applicant's patients reside in Sullivan County and all but one (1) of the MRI providers available to the Applicant's patients are operating at or above capacity -- Bristol Regional Medical Center's scanners each averaged 3223.5 scans in 2011; Holston Valley Medical Center's scanner averaged 3774 scans in 2011; Holston Valley Imaging Center saw 8362 scans (2787.3 per scanner) in 2011; Meadowview Outpatient Diagnostic Center experienced 4457 scans in 2011 (5258 in 2010) using 1 fixed scanner; Sapling Grove Outpatient Diagnostic Center saw 2587 scans in 2011. Volunteer Parkway Imaging Center, located in Bristol, Tennessee, experienced 1327 scans in 2011, but, in order to access this scanner, patients of Medical Care, PLLC would have to travel 21 miles (about a 35 minute drive) from Elizabethton. The only other option would be to travel 21 miles to Erwin, Tennessee to Unicoi County Memorial Hospital (whose MRI utilization in 2011 was 1630 in 2011) for a scan. Only 3.28% of the Applicant's patients reside in Unicoi County. Further, as mentioned above, MSHA is in the process of acquiring Unicoi County Memorial Hospital and has already taken over operational management and financial responsibility.

The market dominance of Mountain States Health Alliance in the Applicant's service area has generated an access issue for patients of Medical Care, PLLC. Mountain States Health Alliance recently implemented an up-front 50% payment requirement for any nonemergency imaging procedure and has been unwilling to make payment options available for the initial 50% prior to scheduling tests such as MRI. In 2011, the average charge per MRI scan in Carter County was $3,776.74 (in 2010, it was $3,483.01).

The 50% up-front payment requirement imposed by Mountain States Health Alliance limits access to MRI services not only for cash paying or uninsured patients, but patients with fixed incomes or with high deductible health plans. Medical Care, PLLC has seen multiple patients choose to forego recommended diagnostic imaging due to the large up-front payment requirement at Mountain States Health Alliance facilities. The Applicant works with its patients to accommodate their financial situations and offers affordable payment plan options for services that might otherwise be unaffordable in a single payment. In addition to offering MRI services at a rate significantly less than the existing provider in Carter County (ranging between $1200 and $2400), Medical Care, PLLC will further reduce the rate by as much as 50% for cash paying or uninsured patients.

The table below represents the average gross charge in 2011 of all MRI providers in the Applicant's service area. Note the substantial (92%) rate increase faced by patients at Mountain States Health Alliance facilities compared to facilities not owned by Mountain States Health Alliance.

County	Facility	Average Gross Charge in 2011
Carter	Sycamore Shoals Hospital*	$3,776.74*
Johnson	Johnson County Community Hospital*	$3,629.35*
Sullivan	Appalachian Orthopaedic Associates – Kingsport	$1,164.61
Sullivan	Appalachian Orthopaedic Associates, PC	$1,064.63
Sullivan	Bristol Regional Medical Center	$2,332.97
Sullivan	Holston Valley Imaging Center, LLC	$2,553.22
Sullivan	Holston Valley Medical Center	$2,125.44

Sullivan	Indian Path Medical Center*	$3,849.93*
Sullivan	Meadowview Outpatient Diagnostic Center	$1,701.49
Sullivan	Sapling Grove Imaging, LLC (Wellmont)	$2,598.00
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,671.94
Sullivan	Volunteer Parkway Imaging Center	$2,365.84
Unicoi	Unicoi County Memorial Hospital	$2,726.90
Washington	Appalachian Orthopaedic Associates – Johnson City	$1,063.86
Washington	Franklin Woods Community Hospital*	$3,810.86*
Washington	Johnson City Medical Center*	$3,853.59*
Washington	Mountain States Imaging at Med Tech Parkway*	$3,718.22*
Washington	Watauga Orthopaedics, PLC	$1,410.16
AVERAGE GROSS CHARGE PER PROCEDURE – ALL facilities		$2,700.78
AVERAGE GROSS CHARGE PER PROCEDURE – owned by Mountain States Health Alliance		$3,773.12
AVERAGE GROSS CHARGE PER PROCEDURE – NOT owned by Mountain States Health Alliance		$1,959.99
% increase in average gross charge		92.51%
**and shading indicates ownership by Mountain States Health Allicance*		

Additionally, Mountain States Health Alliance has elected not to be in network with CIGNA insurance company, a plan offered by several large employers in the area. Employees with CIGNA insurance must travel outside the Mountain States Health Alliance service area to obtain in-network diagnostic tests. Approximately 15% of the Medical Care, PLLC patients with private insurance have Cigna.

Timely scheduling of MRIs for patients at Medical Care, PLLC is also an issue with Mountain States Health Alliance. Per current policy at Sycamore Shoals Hospital, in order to "allow ample time for [its] patients to secure financial clearance," non-emergent cases must be scheduled at least three (3) business days in advance of the scan. For non emergency MRI studies, Medical Care, PLLC providers have seen their patients have to wait several weeks to be scheduled locally or have to drive to a facility outside the county in order to have the MRI scheduled sooner.

2 <u>Every Citizen should have reasonable access to healthcare.</u>

The availability of an alternative MRI provider in Carter County will improve patient access to important diagnostic testing. According to the 2011 summary Joint Annual Report of Hospitals, only 35.7% of Carter County residents obtained care in Carter county (i.e., at Sycamore Shoals Hospital). 59.5%, the vast majority of Carter County residents, sought care in neighboring Washington County. The Carter County Rescue Squad (local ambulance service) routinely transports patients from Carter County to surrounding hospitals for MRI diagnostic scans. This is both inconvenient and an inefficient use of limited healthcare dollars. Access to more convenient, local diagnostic testing is significantly impeded by the lack of alternative imaging providers in the area who, unlike the sole existing provider, do not impose large up-front prepayment requirements, mandatory waiting periods for scheduling of non-emergent scans and offer in-network care.

If approved, Medical Care, PLLC will accept all patients and forms of insurance including TennCare, Medicare, private insurance, cash, and workers comp and will work with patients to accommodate their financial situations and offer affordable payment plan options for services that might otherwise be unaffordable in a single payment. In addition to offering MRI services at a rate significantly less than the existing provider (ranging between $1200 and $2400), the Applicant will further reduce the rate by as much as 50% for cash paying or uninsured patients.

3 The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system;

The current outpatient MRI market in the Applicant's service area is strongly dominated by Mountain States Health Alliance. No viable competitors exist in Carter, Unicoi, Johnson, and Washington Counties. This lack of competition has reduced access, increased the cost and not encouraged efficiencies. As an alternative MRI provider, Medical Care, PLLC would serve as much needed competition in the market, which will increase efficiencies and decrease costs while also increasing patient access to quality healthcare.

Medical Care, PLLC is a participant in One Partner Health Information Exchange (HIE) a program in which Mountain States Health Alliance currently does not participate. One Partner, the local HIE, is designed to share medical information between physicians to improve care and reduce duplication of services. One Partner has over 600 healthcare providers contracted to share patient data. This coordination and collaboration is critical for the future of healthcare. The Applicant will be sharing all patient data associated with imaging studies through One Partner. This improved access to other primary care physicians and specialists is necessary for the continued goal of improved care and decreased costs. MRI which is convenient and cost effective can give the providers at Medical Care, PLLC and in the area the information they need to treat patients in a timely and accurate way. The increase in coordination with specialists translates into reduced patient waiting (which is significant when the patient is suffering in pain, both mental and physical) for proper treatment. Sooner interventions can also reduce severity of illness or disease / injury process.

Medical Care, PLLC is also a primary principal in Qualuable, a Medicare approve shared saving plan Accountable Care Organization (ACO). The ACO is funded only by the savings and efficiencies it produces to Medicare patients. The associated financial risk requires the practice to be able to improve care and drive overall healthcare costs down. MRI services at a site adjacent to Medical Care, PLLC and owned and operated by its principals will improve coordination of care and quality of outcomes at controlled costs.

4 Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers; and

Medical Care, PLLC is a NCQA[5] certified level 3 Patient Centered Medical Home[6]. In order to obtain this level of certification, the practice achieved the highest level of coordinated proactive patient centered care after being evaluated both onsite and offsite according to NCQA standards, known throughout the healthcare industry as being the most rigorous in evaluating quality of care.

Medical Care, PLLC is currently accredited by the American College of Radiology (ACR) for existing imaging modalities of CT and nuclear medicine. Medical Care, PLLC will begin the process to become accredited by ACR immediately following installation of the MRI equipment and training. This ACR accreditation should be completed within the first year of operation and will further signify, inter alia, that the practice is staffed by qualified personnel, has a quality control program and MRI safety policies in place, and that its MRI equipment specifications and performance meet all state and federal requirements.

5 <u>The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.</u>

If this project is approved, Medical Care, PLLC intends to work with National Diagnostic Imaging (NDI) for its MRI interpretations. NDI radiologists are board certified, fellowship trained and licensed in Tennessee. Several have subspecialty in MRI and specifically in neuroradiology. The radiologists meet continuing medical education requirements and maintain current Tennessee licenses.

In addition, Medical Care, PLLC intends to hire 2 radiological technologists with MRI certification.

a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

<u>MAGNETIC RESONANCE IMAGING (MRI)</u>

Standards and Criteria

1. <u>Utilization Standards for non-Specialty MRI Units.</u>

a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a

[5] National Committee for Quality Assurance ("NCQA") is a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups. In Tennessee, all plans contracting with TennCare (Medicaid) must be NCQA Accredited.

[6] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.

Current MRI utilization

Historically, the physicians at Medical Care, PLLC directly order an average of 80 MRI studies per/month (960 MRI studies annually) through the practice's electronic medical record (EMR) system. Additionally, the practice estimates that 24 MRI studies per month (288 MRI studies annually) are directly ordered by the physicians at Medical Care, PLLC but are not captured by the EMR system as they are hand written orders or telephone referrals to MRI providers.

Internal direct ordered MRI = 960 + 288 = 1248

Medical Care, PLLC also refers patients to neurology / neuroscience specialists for MRIs. If the project is approved, these MRIs would be performed at the medical practice. One of these providers, Northeast Tennessee Associate Neurology, estimates that it receives 50 patient referrals from Medical Care, PLLC per month (600 MRI patients annually) who require MRI studies. One other provider, East Tennessee Brain & Spine, estimates that it receives 15-20 patient referrals from Medical Care, PLLC per month (180-240 MRI patients annually -- average 210). Medical Care, PLLC estimates that it refers an additional 16 patients per month (192 annually) to other neurologists for MRI studies.

neurology / neuroscience patient MRI = 600 + 210 + 192 = 1002 studies

In addition, Medical Care, PLLC refers between 75-100 patients per month (or 88 patients on average) to orthopedic specialists. The practice estimates that 40% of these patients will require an MRI for evaluation. Of these patients who require an MRI, the practice estimates that 20% will require an additional MRI post treatment within a year. If this project is approved, Medical Care, PLLC perform these additional MRI studies at the medical practice.

Initial 88pts/mo x 12mo x 40% = 422 initial MRI
422 initial MRI x 20% = 84 repeat MRI
Total orthopedic referral MRI = 506 studies

Total estimated MRI all sources (1,248 + 1,002 + 506) = 2,756

Future MRI utilization

Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annually growth of 5-10%. The MRI will grow consistently with the group and patient volumes.

1st Year estimated MRI studies	*2,756*
2nd year estimated MRI studies (+5% growth)	*2,894*
3rd year estimated MRI studies (+5% growth)	*3,038*
4th year estimated MRI studies (+5% growth)	*3,190*
5th year estimated MRI studies (+5% growth)	*3,350*

b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

Not applicable.

c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

Not applicable.

d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.

Not applicable.

e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

Not applicable.

2. <u>Access to MRI Units.</u> All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

As indicated above, the Applicant's proposed MRI scanner will be located in the same building where the Elizabethton office of Medical Care, PLLC is located. In 2011, Medical Care, PLLC saw a total of 23,483 patients. 10,754 (45.79%) of the patients resided in Carter County. 8,856 (37.71%) of the patients resided in Washington County. 1,333 (5.68%) of the patients resided in Sullivan County. 911 (3.88%) of the patients resided in Johnson County. 771 (3.28%) of the patients resided in Unicoi County. 858 (3.65%) of the patients resided outside the proposed service area.

At Medical Care, PLLC, the county of origin for patients for the years 2009 through 2011 was as follows:

County	Year		
	2009	2010	2011
Carter	9,557	8,857	9,326
Washington	3,028	2,776	2,264
Sullivan	567	522	514
Johnson	556	536	617
Unicoi	323	304	290
Other	455	393	341
TOTAL	**14,486**	**13,388**	**13,712**

Given the experience of Medical Care, PLLC at the Elizabethton office, the proposed location of the MRI unit will prove accessible to at least 75% of the service area's population.

3. <u>Economic Efficiencies</u>. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

In Carter County, Tennessee, where the proposed MRI will be located, there is currently only one (1) provider offering MRI services, namely, Sycamore Shoals Hospital. This facility has not been willing to partner in radiology services in the past. Further, the Applicant anticipates that continued reliance on this facility for referral of patients of Medical Care, PLLC for imaging presents patient access issues as described elsewhere in this application given the 50% up-front payment requirement, substantial charges for MRI scans at the facility, and out-of-network status for patients with CIGNA insurance. Scheduling delays and inconvenient appointment options would also remain an issue for Medical Care, PLLC patients. Physical separation from other radiology services offered on site by Medical Care, PLLC would continue to prove inconvenient for patients of Medical Care, PLLC if they were to be referred to off site imaging providers.

The Applicant considered the possibility of establishing a mobile MRI service. However, patients would be exposed to the elements (rain & snow etc.) in order to access the mobile unit and would encounter less desirable handicap access (wheelchair lift versus ground level). Additionally, the confined space in a trailer would exacerbate anxiety issues already faced by claustrophobic patients requiring an MRI. The Applicant found that initial cost evaluations associated with the purchase of a fixed magnet would not be avoided with the purchase of a mobile unit as there would be significant build-out costs for modifications to parking, to provide weight support for the trailer, and ensure adequate and appropriate electrical supply. The proposed location would also have limited physical space for parking a mobile trailer close to the current radiology area.

The Applicant believes that its purchase of the reconditioned GE Signa 1.5 Tesla from Oxford Instruments Service, LLC for $399,000.00 (excluding tax) presents the most advantages in terms of cost savings, increased efficiencies and exposure to financial risk. GE was selected because of the large market dominance in the MRI equipment market. There are many resources for parts and service and GE has a long and stable medical equipment history. The cost of a new comparable 1.5 Tesla MRI is $1.4 million plus options. GE priced a refurbished 1.5 Tesla MRI for $500,000. The cost for the MRI from Oxford Instruments Service, LLC is $1 million less than purchase of a new unit and 20% less than purchasing a refurbished unit through GE. The ongoing maintenance cost for the refurbished MRI is also less than maintenance for a new MRI.

4. <u>Need Standard for non-Specialty MRI Units</u>.
A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelvemonth period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year

Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

The proposed service area is comprised of Carter, Johnson, Unicoi, Sullivan and Washington counties in Tennessee. With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration. In Johnson, Carter and Unicoi counties, the entire county is designated as a MUA. Carter County and Unicoi County each have only one (1) MRI provider. Johnson County has only one (1) MRI provider, namely, Johnson County Community Hospital, but the MRI unit is mobile (as opposed to fixed) and operates only two (2) days per month.

The combined average utilization of existing MRI providers in all of the counties comprising the service area in 2011 was 1,821. Excluding Johnson County, which only offers mobile MRI service two (2) days per month, the combined average utilization in the proposed service area in 2011 was 2208. Excluding additionally private physician offices and specialty MRIs (i.e., standup or extremity only), the combined average utilization in the proposed service area in 2011 was 2,451. Essentially, the existing providers in the proposed service area were near 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve month period reflected in the provider medical equipment report maintained by the HSDA. (see table below).

County	Facility and Type	Number of MRI Scanners and Type	Total Procedures		
			2009	2010	2011
Washington	Franklin Woods Community Hospital (HOSP)	1 Fixed	0	1635	3546
Washington	Johnson City Medical Center (HOSP)	2 Fixed	5186 (avg. 2593 per scanner)	6596 (avg. 3298 per scanner)	7247 (avg. 3623.5 per scanner)
Washington	Mountain States Imaging at Med Tech Parkway (ODC)	1 Fixed	2162	2066	2738
Washington	Watauga Orthopaedics, PLC (PO)	1 Fixed	3284	2927	2748
Washington	Appalachian Orthopaedic Associates - Johnson City (PO)	1 Fixed	639	521	546
Combined average utilization of existing MRI providers in Washington County in 2011					2,804
Combined average utilization in Washington County excluding PO in 2011					3256
Sullivan	Appalachian Orthopaedic Associates – Kingsport (PO)	1 Fixed	1396	1293	1460
Sullivan	Appalachian Orthopaedic Associates, PC (PO)	1 Fixed	400	365	288
Sullivan	Bristol Regional Medical Center (HOSP)	2 Fixed	5904 (avg. 2952 per scanner)	6168 (avg. 3084 per scanner)	6447 (avg. 3223.5 per scanner)
Sullivan	Holston Valley Imaging Center, LLC (ODC)	3 Fixed	9367 (avg. 3122.3 per scanner)	8025 (avg. 2675 per scanner)	8362 (avg. 2787.3 per scanner)
Sullivan	Holston Valley Medical Center (HOSP)	1 Fixed	4026	3624	3774
Sullivan	Indian Path Medical Center	1 Fixed	2697	2700	2651
Sullivan	Meadowview Outpatient Diagnostic Center	1 Fixed	4440	5258	4457
Sullivan	Wellmont Sapling Grove Imaging, LLC (Stand up MRI) (HImaging)	1 Fixed	656	536	349
Sullivan	Sapling Grove Outpatient Diagnostic Center (ODC)	1 Fixed	2588	2116	2587
Sullivan	Volunteer Parkway Imaging Center (HODC)	1 Fixed	1279	1193	1327
Combined average utilization of existing MRI providers in Sullivan County in 2011					2439
Combined average utilization in Sullivan County excluding standup and PO in 2011					2961
Unicoi	Unicoi County Memorial Hospital, Inc. (HOSP)	1 Fixed	967	959	1630
Combined average utilization of existing MRI providers in Unicoi County in 2011					1630
Johnson	Johnson County Community Hospital (HOSP)	1 Mobile (2 days/month)	255	256	274
Combined average utilization of existing MRI providers in Johnson County in 2011					274
Carter	Sycamore Shoals Hospital (HOSP)	1 Fixed	2276	2026	1958
Combined average utilization of existing MRI providers in Carter County in 2011					1958

5. Need Standards for Specialty MRI Units.

a. Dedicated fixed or mobile Breast MRI Unit. **An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:**

1. **It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;** *Not applicable*

2. **Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;** *Not applicable*

3. **It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.** *Not applicable*

4. **It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.** *Not applicable*

b. Dedicated fixed or mobile Extremity MRI Unit. **An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.**
Not applicable

c. Dedicated fixed or mobile Multi-position MRI Unit. **An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.** *Not applicable*

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes. *Noted*

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.

a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

See Attachment B.II.E.1.a.4. The proposed MRI Unit has been approved for use by the FDA.

b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Appropriate location of the magnet, installation of proper safety mechanisms, and documentation, training and implementation of all appropriate safety policies and procedures applicable in federal standards, manufacturer's specifications and licensing agencies will be established and enforced.

c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.

The Applicant will adhere to the ACR Guidance Document for Safe MR Practices published by the American College of Radiology included in Attachment C.1.a.MRI Standards and Criteria 7.c. A physician will be on premises and technician(s) appropriately trained in emergency response procedures will be present when patients are being scanned. A crash cart stocked with appropriate equipment and medications will be maintained at all times.

d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.

The Applicant will adhere to the ACR Practice Guideline For Performing And Interpreting Magnetic Resonance Imaging (MRI) included in Attachment C.1.a.MRI Standards and Criteria 7.d.

e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or

is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

The Applicant is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

Medical Care, PLLC will begin the process to become ACR accredited immediately following installation of the MRI equipment and training of staff. This ACR accreditation should be completed within the first year of operation.

g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Medical Care, PLLC will use IPC, a local hospitalist group, for any necessary hospital admissions. IPC maintains privileges and access to all area hospitals in the Mountain States Health Alliance (MSHA) facilities as well as Wellmont facilities and will cover the Applicant's patients as needed. Please see the letter from IPC included as Attachment C.1.a. MRI Standards and Criteria 7.g.

h. The applicant must provide supervision and interpretation by a board certified radiologist or physician demonstrating experience and training in the relevant imaging procedure, with certification by the appropriate regulatory body

Medical Care, PLLC will use National Diagnostic Imaging (NDI) for its MRI interpretations. NDI radiologists are board certified, fellowship trained and licensed in Tennessee. Several have subspecialty in MRI and specifically in neuroradiology. The radiologists meet continuing medical education requirements and maintain current Tennessee licenses.

8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

If approved, Medical Care , PLLC will submit all data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No.2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration?

With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration. In Johnson, Carter and Unicoi counties, the entire county is designated as a MUA. In Washington County, only the Bethesda Division Service Area is deemed an MUA.

b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

Not applicable.

c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

The Applicant is the largest TennCare provider in Carter County and already contracts with all TennCare MCOs. The Applicant also participates in the Medicare program. 31.24% of the patients seen at Medical Care, PLLC for the period November 20, 2011 through November 20, 2012, were TennCare enrollees. During the same period 9.49% of the patients seen at Medical Care, PLLC were Medicare enrollees.

In Tennessee, all plans contracting with TennCare (Medicaid) must be accredited by the National Committee for Quality Assurance ("NCQA"), a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups. Medical Care, PLLC is a NCQA certified level 3 Patient Centered Medical Home[7]*.*

Additionally, Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program.

d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

---

[7] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

Medical Care, PLLC is a multi-specialty medical practice with 17 physicians and 14 physician extenders in specialties that include family practice, general practice, internal medicine, general surgery, gynecology and pediatrics. Elderly and pediatric patients account for approximately one-third (1/3) of all patients at Medical Care, PLLC (19% of patients are over 60 years old; 12% of patients are less than 10 years old). As one of the largest TennCare providers, the practice also sees many mentally and physically disabled children in State custody. Further, the practice cares for the brain injured residents of Crumley House and adults with intellectual and developmental disabilities at Dawn of Hope and Envision. All of these patients do typically require longer preparation and scanning times, however, the practice does not anticipate that care of these patients will negatively affect its ability to meet the need standard for MRI scans.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

The project is consistent with the long-range plans of the Applicant as it will enable the physicians at Medical Care, PLLC to provide more comprehensive care to their patients in a more cost effective manner and increase patient access and convenience. Medical Care, PLLC has always focused on patient centered care. Medical Care's motto is "Medical care with a heart" which also ties into the company's heart logo. Medical Care was the first walk-in physician office in Carter County and is open on evenings and weekends. Medical Care has always focused on the highest quality while maintaining cost competiveness. As medical Care has grown, it has continued to add additional services and become comprehensive in ancillary services which also add to patient convenience and access. The practice implemented its current electronic medical records (EMR) system in 1997 and was one of the first adopters of this technology in Tennessee. The practice has continued to adopt technology whichs aid in coordination with other physicians through its past partnership in CareSpark and its current participation with One Partner, the local health information exchange (HIE). MRI is the next logical addition in this long term plan to provide high quality, comprehensive services which are accessible and convenient to all patients. Having MRI will also improve patient coordination of imaging services and decrease treatment times. MRI will also allow Medical Care to control costs as we continue to transition from a current fee for service (quantity) reimbursement to a quality based reimbursement models.

Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program. Qualuable Medical Professionals has a triple aim to reform healthcare, namely, to improve service, to improve quality, and to lower costs. The ability to offer MRI services at the same site where other diagnostic modalities are available to Medical Care, PLLC providers for their patients, including x-ray, ultrasound, nuclear medicine, bone densitometry (DXA), mammography and computed tomography (CT), will further all three of these goals by resulting in comprehensive coordinated results, control of patient quality of care and service and direct control over cost.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the

service area. Please submit the map on 81/2" x 11" sheet white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

The proposed service area is comprised of Carter, Johnson, Unicoi, Sullivan and Washington counties in Tennessee. In 2011, Medical Care, PLLC saw a total of 23,483 patients. 10,754 (45.79%) of the patients resided in Carter County. 8,856 (37.71%) of the patients resided in Washington County. 1,333 (5.68%) of the patients resided in Sullivan County. 911 (3.88%) of the patients resided in Johnson County. 771 (3.28%) of the patients resided in Unicoi County. 858 (3.65%) of the patients resided outside the proposed service area. A county level map of the State of Tennessee marked to reflect the service area is included as Attachment C.3.

4. A. Describe the demographics of the population to be served by this proposal.

The Applicant's proposed service area is comprised of Carter, Johnson, Unicoi, Sullivan and Washington counties in Tennessee. The area is home to roughly 375,468 people, with 57,185 in Carter County, 18,231 in Johnson County, 18,280 in Unicoi, 157,419 in Sullivan, and 124,353 in Washington County in 2011 according to the US Census Bureau.

Compared nationally, there is a low level of diversity in the proposed service area. The racial makeup of the counties in the service area is summarized in the table below:

County	White	Black	American Indian and Alaska Native	Asian	Hispanic or Latino	Persons reporting 2 or more races
Carter	96.7%	1.6%	.2%	.3%	1.6%	1.2%
Johnson	96.4%	2.2%	.2%	.2%	1.6%	.9%
Sullivan	95.4%	2.4%	.3%	.6%	1.6%	1.2%
Unicoi	98.1%	.4%	.4%	.2%	4.1%	1.0%
Washington	92.6%	4.2%	.4%	1.2%	3.0%	1.5%
Tennessee	79.5%	16.9%	.4%	1.5%	4.7%	1.6%
USA	78.1%	13.1%	1.2%	5.0%	16.7%	2.3%
Source: U.S. Census Bureau. State and County Quick Facts: Tennessee. Available at http://quickfacts.census.gov/qfd/states/, Accessed January 21, 2013.						

The service area shows a large elderly population and low median household income compared to Tennessee and the US as well as a lower level of educational attainment compared to the rest of the state and country. Age, gender, high school attainment and median household income data for the counties in the service area in the year 2011 are summarized in the table below:

County	Male	Female	Persons under 18	Persons 65 and over	Median Age	High School Graduate or Higher	Median Household Income (2007-2011)
Carter	48.9%	51.1%	19.9%	17.4%	42.0	78.6%	$32,148
Johnson	53.7%	46.3%	18.1%	18.6%	42.7	70.1%	$32,159
Sullivan	48.4%	51.6%	20.3%	19.0%	43.2	82.7%	$40,572
Unicoi	48.9%	51.1%	20.0%	19.9%	44.6	75.3%	$35,265
Washington	48.3%	51.7%	19.9%	15.7%	39.3	85.1%	$42,104

Tennessee	48.7%	51.3%	23.3%	13.7%	39.5	83.2%	$43,989
USA	49.2%	50.8%	23.7%	13.2%	36.9	85.4%	$52,762
Source: U.S. Census Bureau. State and County Quick Facts: Tennessee. Available at http://quickfacts.census.gov/qfd/states/, Accessed January 21, 2013.							

The service area also shows a higher level of unemployment (with the exception of Sullivan and Washington Counties) and population of uninsured compared to the rest of the state and country.

County	2011 Level of Unemployment*	Percent of population under age 65 without health insurance**
Carter	9.1%	19%
Johnson	12.0%	22%
Sullivan	7.7%	15%
Unicoi	9.7%	16%
Washington	7.8%	17%
Tennessee	9.2%	16%
USA	8.9%	11%
**Source: USDA Economic Research Service, available at http://www.ers.usda.gov/data-products/county-level-data-sets/unemployment.aspx*		
***Source: University of Wisconsin Population Health Institute and the Robert Wood Johnson Foundation (RWJF), available at www.countyhealthrankings.org*		

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Medical Care, PLLC's participation in the TennCare and Medicare programs helps serve the special needs of the service area population, which, as indicated above, shows a large elderly population and low median household income compared to Tennessee and the US as well as a lower level of educational attainment compared to the rest of the state and country. Approval of this project will improve the population's access to diagnostic tests that can improve patient outcomes in both surgical and non surgical cases.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

There are no approved but unimplemented CONs of similar institutions in the service area. The existing MRI providers in the service area, number of scanners and type and utilization for the years 2009, 2010 and 2011 are indicated in the table below (the names of facilities owned or controlled by Mountain States Health Alliance are underlined):

County	Facility and Type	Number of MRI Scanners and Type	Total Procedures		
			2009	2010	2011
Washington	Franklin Woods Community Hospital (HOSP)	1 Fixed	0	1635	3546
Washington	Johnson City Medical Center (HOSP)	2 Fixed	5186 (avg. 2593 per scanner)	6596 (avg. 3298 per scanner)	7247 (avg. 3623.5 per scanner)
Washington	Mountain States Imaging at Med Tech Parkway (ODC)	1 Fixed	2162	2066	2738
Washington	Watauga Orthopaedics, PLC (PO)	1 Fixed	3284	2927	2748
Washington	Appalachian Orthopaedic Associates - Johnson City (PO)	1 Fixed	639	521	546
Combined average utilization of existing MRI providers in Washington County in 2011					2,804
Combined average utilization in Washington County excluding PO in 2011					3256
Sullivan	Appalachian Orthopaedic Associates – Kingsport (PO)	1 Fixed	1396	1293	1460
Sullivan	Appalachian Orthopaedic Associates, PC (PO)	1 Fixed	400	365	288
Sullivan	Bristol Regional Medical Center (HOSP)	2 Fixed	5904 (avg. 2952 per scanner)	6168 (avg. 3084 per scanner)	6447 (avg. 3223.5 per scanner)
Sullivan	Holston Valley Imaging Center, LLC (ODC)	3 Fixed	9367 (avg. 3122.3 per scanner)	8025 (avg. 2675 per scanner)	8362 (avg. 2787.3 per scanner)
Sullivan	Holston Valley Medical Center (HOSP)	1 Fixed	4026	3624	3774
Sullivan	Indian Path Medical Center	1 Fixed	2697	2700	2651
Sullivan	Meadowview Outpatient Diagnostic Center	1 Fixed	4440	5258	4457
Sullivan	Wellmont Sapling Grove Imaging, LLC (Stand up MRI) (HImaging)	1 Fixed	656	536	349
Sullivan	Sapling Grove Outpatient Diagnostic Center (ODC)	1 Fixed	2588	2116	2587
Sullivan	Volunteer Parkway Imaging Center (HODC)	1 Fixed	1279	1193	1327
Combined average utilization of existing MRI providers in Sullivan County in 2011					2439
Combined average utilization in Sullivan County excluding standup and PO in 2011					2961
Unicoi	Unicoi County Memorial Hospital, Inc. (HOSP)	1 Fixed	967	959	1630
Combined average utilization of existing MRI providers in Unicoi County in 2011					1630
Johnson	Johnson County Community Hospital (HOSP)	1 Mobile (2 days/month)	255	256	274
Combined average utilization of existing MRI providers in Johnson County in 2011					274
Carter	Sycamore Shoals Hospital (HOSP)	1 Fixed	2276	2026	1958
Combined average utilization of existing MRI providers in Carter County in 2011					1958

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Current MRI utilization

Historically, the physicians at Medical Care, PLLC directly order an average of 80 MRI studies per/month (960 MRI studies annually) through the practice's electronic medical record (EMR) system. Additionally, the practice estimates that 24 MRI studies per month (288 MRI studies annually) are directly ordered by the physicians at Medical Care, PLLC but are not captured by the EMR system as they are hand written orders or telephone referrals to MRI providers.

Internal direct ordered MRI = 960 + 288 = 1248

Medical Care, PLLC also refers patients to neurology / neuroscience specialists for MRIs. If the project is approved, these MRIs would be performed at the medical practice. One of these providers, Northeast Tennessee Associate Neurology, estimates that it receives 50 patient referrals from Medical Care, PLLC per month (600 MRI patients annually) who require MRI studies. One other provider, East Tennessee Brain & Spine, estimates that it receives 15-20 patient referrals from Medical Care, PLLC per month (180-240 MRI patients annually -- average 210). Medical Care, PLLC estimates that it refers an additional 16 patients per month (192 annually) to other neurologists for MRI studies.

neurology / neuroscience patient MRI = 600 + 210 + 192 = 1002 studies

In addition, Medical Care, PLLC refers between 75-100 patients per month (or 88 patients on average) to orthopedic specialists. The practice estimates that 40% of these patients will require an MRI for evaluation. Of these patients who require an MRI, the practice estimates that 20% will require an additional MRI post treatment within a year. If this project is approved, Medical Care, PLLC perform these additional MRI studies at the medical practice.

Initial 88pts/mo x 12mo x 40% = 422 initial MRI
422 initial MRI x 20% = 84 repeat MRI
Total orthopedic referral MRI = 506 studies

Total estimated MRI all sources (1,248 + 1,002 + 506) = 2,756

Future MRI utilization

Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annually growth of 5-10%. The MRI will grow consistently with the group and patient volumes.

1st Year estimated MRI studies	*2,756*
2nd year estimated MRI studies (+5% growth)	*2,894*
3rd year estimated MRI studies (+5% growth)	*3,038*

4th year estimated MRI studies (+5% growth) 3,190
5th year estimated MRI studies (+5% growth) 3,350

Economic Feasibility

1. Provide the cost of the project by completing the Project Costs Chart on the following page.

Justify the cost of the project.

- **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee**

- **The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.**

- **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

- **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

Projected costs are set forth on the Project Cost Chart included as Attachment C Economic Feasibility 1. The project is estimated to cost $838,543. This includes the fair market value ($23,590 x 5 years) / the total amount of the lease payments over the initial term of the lease ($1,965.83x60 months) in the amount of $117,950, legal fees totaling $15,000, the construction costs in the amount of $80,220, the cost of the GE Signa Excite 1.5 Tesla stationary magnetic resonance imaging ("MRI") scanner for $399,000, taxes in the amount of $27,984, and computers and software, and office furniture in the amount of $3,000. A letter from Design Build Construction is included to support the construction costs.

2. **Identify the funding sources for this project.**

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the

application, in correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

X **A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**
A letter from State of Franklin Bank stating favorable initial contact, the proposed loan amount, expected interest rates, anticipated term of the loan, and conditions is included as Attachment Economic Feasibility 2.A.

__ **B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**
__ **C. General Obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.**
__ **D. Grants--Notification of intent form for grant application or notice of grant award; or**
X **E. Cash Reserves--Appropriate documentation from Chief Financial Officer.**
__ **F. Other—Identify and document funding from all other sources.**

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

The total project cost for this proposal is $838,543. The total estimated construction cost to modify the existing 674 square feet of space that will house the MRI is $80,220. This is a construction cost of $119 per square foot, which is reasonable in relation to other projects approved by the Health Services and Development Agency.

State of Franklin Healthcare Associates Outpatient Diagnostic Center
CN0212-122
Approved April 26, 2003
Total cost: $4,312,481
Construction costs: $562,500
Square feet: 1,875
Construction cost per square foot: $300

Coffee County Hospital Group dba Medical Center of Manchester
CN1012-054 and CN0607-049
Approved February 23, 2011
Construction Cost: $180,883
Square feet: 1,680
Construction cost per square foot: $107.67

Tennessee Oncology, PLLC
CN1110-041

Approved January 25, 2012
Square feet: 450
Construction cost $405,000
Construction cost per square foot: $900

4. Complete Historical and Projected Data Charts on the following two pages--*Do not modify the Charts provided or submit Chart substitutions!* Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

The Historical Data Chart and the Projected Data Chart have been completed and are included as Attachment C Economic Feasibility 4.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

The project's average gross charge will be $1584.55 for MRI's, with the provision for charity and bad debt averaging $691.89(43.66%) per scan, the average net charge then becomes $892.66.

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

As the proposal involves a new service (MRI), there are no current charge schedules and no projected adjustment to current charges. The average projected gross charge, average projected deduction (including projected contractual adjustments, provision for charity care and bad debts), the average projected net charge, and the anticipated revenue from the proposed project for the two years following completion are presented in the table below as well as in the Projected Data Chart.

	Year 1	Year 2
Average Gross Charge	$1585.55	$1584.55
Average Projected Deduction	691.89	691.89
Average Projected Net Charge	892.66	892.66
Anticipated Gross Operating Revenue	4,369,775.80	4,588,581.70
Anticipated Net Operating Revenue	2,462,927.00	2,586,252.10

B. Compare the proposed charges to those of similar facilities in the service

area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

The Applicant's proposed charges (average $1,584.55) are reasonable in relation to those of similar facilities in the service area (average $2,700.78 in 2011) as demonstrated in the tables below.

CPT	Gross MRI Charges Proposed by Medical Care, PLLC	Charge
70551	MRI HEAD W/O CONTRAST	$1,400.00
70552	MRI HEAD W/ CONTRAST	$1,640.00
70553	MRI HEAD W/ & W/O CONTRAST	$2,060.00
71550	MRI CHEST W/O CONTRAST	$1,400.00
71551	MRI CHEST W CONTRAST	$1,640.00
71552	MRI CHEST W & W/O CONTRAST	$2,200.00
72141	MRI CERVICAL SPINE W/O CONTRAST	$1,250.00
72142	MRI CERVICAL SPINE W/ CONTRAST	$1,500.00
72146	MRI THORACIC SPINE W/O CONTRAST	$1,400.00
72147	MRI THORACIC SPINE W/ CONTRAST	$1,500.00
72148	MRI LUMBAR SPINE W/O CONTRAST	$1,300.00
72149	MRI LUMBAR SPINE W/ CONTRAST	$1,600.00
72156	MRI C SPINE W/ & W/O CONTRAST	$2,000.00
72157	MRI T SPINE W/ & W/O CONTRAST	$2,000.00
72158	MRI L SPINE W/ & W/O CONTRAST	$2,000.00
72195	MRI PELVIS W/O CONTRAST	$1,250.00
72196	MRI PELVIS W CONTRAST	$1,500.00
72197	MRI PELVIS W & W/O CONTRAST	$1,900.00
73218	MRI UPPER EXTREMITY W/O CONTRAST	$1,200.00
73219	MRI UPPER EXTREMITY W CONTRAST	$1,450.00
73220	MRI UPPER EXTREMITY W & W/O CONTRAST	$1,750.00
73221	MRI UPPER EXTREMITY JOINT W/O CONTRAST	$1,200.00
73222	MRI UPPER EXTREMITY JOINT W CONTRAST	$1,400.00
73223	MRI UPPER EXTREMITY JOINT W & W/O CONTRAST	$1,900.00
73718	MRI LOWER EXTREMITY W/O CONTRAST	$1,200.00
73719	MRI LOWER EXTREMITY W CONTRAST	$1,400.00
73720	MRI LOWER EXTREMITY W & W/O CONTRAST	$1,750.00
73721	MRI LOWER EXTREMITY JOINT W/O CONTRAST	$1,200.00

73722	MRI LOWER EXTREMITY JOINT W CONTRAST	$1,350.00
73723	MRI LOWER EXTREMITY JOINT W & W/O CONTRAST	$1,950.00
74181	MRI ABDOMEN W/O CONTRAST	$1,400.00
74182	MRI ABDOMEN W CONTRAST	$1,600.00
74183	MRI ABDOMEN W & W/O CONTRAST	$2,000.00
	AVERAGE GROSS CHARGE PER PROCEDURE	$1,584.55

County	Facility	Average Gross Charge in 2011
Carter	Sycamore Shoals Hospital	$3,776.74
Johnson	Johnson County Community Hospital	$3,629.35
Sullivan	Appalachian Orthopaedic Associates – Kingsport	$1,164.61
Sullivan	Appalachian Orthopaedic Associates, PC	$1,064.63
Sullivan	Bristol Regional Medical Center	$2,332.97
Sullivan	Holston Valley Imaging Center, LLC	$2,553.22
Sullivan	Holston Valley Medical Center	$2,125.44
Sullivan	Indian Path Medical Center	$3,849.93
Sullivan	Meadowview Outpatient Diagnostic Center	$1,701.49
Sullivan	Sapling Grove Imaging, LLC (Wellmont)	$2,598.00
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,671.94
Sullivan	Volunteer Parkway Imaging Center	$2,365.84
Unicoi	Unicoi County Memorial Hospital	$2,726.90
Washington	Appalachian Orthopaedic Associates – Johnson City	$1,063.86
Washington	Franklin Woods Community Hospital	$3,810.86
Washington	Johnson City Medical Center	$3,853.59
Washington	Mountain States Imaging at Med Tech Parkway	$3,718.22
Washington	Watauga Orthopaedics, PLC	$1,410.16
AVERAGE GROSS CHARGE PER PROCEDURE		$2,700.78

The table below represents the average gross charge in 2011 of all MRI providers in the Applicant's service area. Note the substantial (92%) rate increase faced by patients at Mountain States Health Alliance facilities compared to facilities not owned by Mountain States Health Alliance.

County	Facility	Average Gross Charge in 2011
Carter	Sycamore Shoals Hospital*	$3,776.74*
Johnson	Johnson County Community Hospital*	$3,629.35*
Sullivan	Appalachian Orthopaedic Associates – Kingsport	$1,164.61
Sullivan	Appalachian Orthopaedic Associates, PC	$1,064.63
Sullivan	Bristol Regional Medical Center	$2,332.97
Sullivan	Holston Valley Imaging Center, LLC	$2,553.22
Sullivan	Holston Valley Medical Center	$2,125.44
Sullivan	Indian Path Medical Center*	$3,849.93*
Sullivan	Meadowview Outpatient Diagnostic Center	$1,701.49
Sullivan	Sapling Grove Imaging, LLC (Wellmont)	$2,598.00
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,671.94
Sullivan	Volunteer Parkway Imaging Center	$2,365.84
Unicoi	Unicoi County Memorial Hospital	$2,726.90

Washington	Appalachian Orthopaedic Associates –Johnson City	$1,063.86
Washington	Franklin Woods Community Hospital*	$3,810.86*
Washington	Johnson City Medical Center*	$3,853.59*
Washington	Mountain States Imaging at Med Tech Parkway*	$3,718.22*
Washington	Watauga Orthopaedics, PLC	$1,410.16
AVERAGE GROSS CHARGE PER PROCEDURE – ALL facilities		$2,700.78
AVERAGE GROSS CHARGE PER PROCEDURE – owned by Mountain States Health Alliance		$3,773.12
AVERAGE GROSS CHARGE PER PROCEDURE – NOT owned by Mountain States Health Alliance		$1,959.99
% increase in average gross charge		92.51%
**and shading indicates ownership by Mountain States Health Allicance*		

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Projected utilization is based on current utilization rates of MRI services of Medical Care, PLLC patients and the historic rate of growth in patients at the medical practice. The Projected Data Chart outlines the cost-effectiveness of the proposal. A positive cash flow is expected in the first year of operation.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Revenue and expense information for this proposal for Years 1 and 2 following project completion is included in the Projected Data Chart. The net operating income less capital expenditures as represented is projected to be $978,024 in year 1 and $1,023,856 in year 2.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Medical Care, PLLC is both a TennCare and Medicare provider. In the previous year, during the period November 20, 2011 to November 20, 2012, 31.24% of the patients treated at Medical Care, PLLC were TennCare enrollees. During the same period, 9.49% of the patients were on Medicare. Private insurance accounted for 38.55% of the patients, Worker's Compensation accounted for 5.36% of the patients and private pay accounted for 14.71% of the patients. Medical Care, PLLC anticipates seeing a similar payor mix in the future.

The estimated dollar amount of revenue and percentage of total project revenue anticipated from TennCare and Medicare for the proposals first year of operation is set forth below (note that Medical Care, PLLC typically sees TennCare and Medicare patients more frequently than other patient populations because they tend to have more chronic conditions. Accordingly, the percentage of anticipated revenue from TennCare and Medicare reflected below is higher than the percentage of patients noted above. The percentage of anticipated revenue is based on the medical practice's current percentage of TennCare/Medicare revenue for patient visits.):

	TennCare	Medicare
Gross TennCare and Medicare MRI Revenues	$1,359,000.34	$1,214,797.73
% of Total MRI Revenues	31.1%	27.8%

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

The most recent balance sheet and income statement for Medical Care, PLLC and Pine Palms Management, LLC are attached as requested and labeled Attachment C Economic Feasibility 10.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

Options Considered by Medical Care, PLLC include:

Option One: Maintain the status quo/do nothing -- This alternative does not address the issues that Medical Care, PLLC is attempting to resolve with its application and will result in continued patient delays and inconvenience, and reduced patient access.

Option Two: Partnering with other area MRI providers -- Sycamore Shoals Hospital is the only existing MRI provider in Carter County and it has not been willing to partner in radiology services the past. This alternative also does not solve the delays and patient access issues currently being experienced. Physical separation from other radiology services provided at Medical Care, PLLC would lead to increased patient inconvenience.

Option Three: Establishing a mobile MRI service -- this alternative is not optimal operationally or clinically and will not meet the current and growing patient care needs of Medical Care, PLLC. Initial cost evaluations are similar to those of a fixed magnet -- a mobile unit would still require significant build-out costs for modifications to parking, weight support of trailer, electric supply, etc. Further, there is limited physical space for parking a mobile trailer close to the radiology area of the practice. Patients would be exposed to the elements (rain & snow etc.) in order to access the mobile unit. Handicapped patients would have to use a wheelchair lift to access the mobile unit rather than having ground level access to a fixed unit.

a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Medical Care, PLLC considered whether other less costly, more effective/efficient options existed. Medical Care, PLLC considered acquiring a lower cost extremities only MRI, but after reviewing the imaging needs of its patients, the practice concluded that the significant limitations

associated with an extremities only MRI would not meet the needs of its patients and would also greatly reduce its utilization of an MRI which would decrease efficiency.

The practice also considered an open, low powered MRI. Medical Care determined that, while these systems can be less expensive initially, they have reduced quality images, particularly in neurologic studies and imaging larger patients. Since quality and patient care is our highest priority, this option was found insufficient to meet patients' needs.

Medical Care, PLLC considered partnering with other physicians or current MRI service providers. However, Medical Care is located in a rural area with limited physician groups willing to partner in providing MRI services. The local hospital has been unwilling to partner in their current MRI services.

Medical Care, PLLC considered utilizing a mobile MRI service. This alterative would require significant modification to the parking lot and electrical service. Patients would be exposed to inclement weather (rain and snow), which would increase the risk of injury. Further, the mobile services which are housed in trailers can exacerbate symptoms for claustrophobic patients and prove less accessible for handicapped and injured patients. In reviewing pricing for mobile service, Medical Care, PLLC found that there was not a significant cost savings and the estimated patient load would require it to be parked permanently. After review, this option was eliminated due to several problems without any savings.

Medical Care, PLLC considered the option to do nothing and maintain the status quo, but this would result in continued patient delays in scheduling, large up-front fee deposits required prior to scheduling, and out of network issues for CIGNA patients. Doing nothing would also maintain the patient inconvenience factor as patients would still be likely to travel to out of county facilities for scans. Doing nothing will continue the lack of patient coordination and timely treatment.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Alternatives to new construction (i.e., sharing arrangements and mobile unit) were considered as previously noted. Construction for this proposed project is limited to renovation of existing space.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

The Applicant will continue to work closely with other healthcare providers in the area including: Mountain States Health Alliance hospitals, Wellmont Health Systems, East Tennessee

State University, Lincoln Memorial University, local nursing homes, clinics and other healthcare providers, Medicare and all managed care plans in the area including Blue Cross Blue Shield, United Healthcare, Cigna, Crest Point, Highlands IPA, and Qualuable (ACO).

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

The proposal is beneficial to the health care system and will result in minimal to no negative effects from unnecessary duplication of services. Patients will benefit from having an additional MRI provider in the area in many ways including, shorter wait times, improved convenience, expedited diagnosis and treatment. As previously noted, the lack of competition in the service area has reduced access, increased costs and not encouraged efficiencies.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

The anticipated staffing pattern for employees at the outpatient diagnostic center is summarized below along with a comparison of the salaries proposed to prevailing wage patterns in the service area as published in May 2012 by the Tennessee Department of Labor & Workforce Development.

					Compared to Johnson City, TN Healthcare Practitioners and Technical Occupations*			
Position	**Year 1 FTE**	**Year 2 FTE**	**Proposed Hourly Pay Range**	**Average**	**Entry**	**Above Entry**	**Median**	**Above Median**
MRI Tech	2	2.5	$24-$27	$25.50	$17.85	143%	$22.20	115%
Management	1	1	$14-$18	$16.00	$12.50	128%	$18.55	86%
Support Staff	2	2	$9-$12	$10.50	$8.20	128%	$10.65	99%
Service/ Marketing	1	1	$12-$14	$13.00	$8.05	161%	$13.50	96%

**Source: TN Dept. of Labor & Workforce Development, Employment Security Division, Labor Market Information*

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Medical Care, PLLC does not anticipate that finding appropriately licensed staff will be a problem as the practice receives many resumes of experienced technologists looking for work.

Moreover, East Tennessee State University has a program training new 4 year technologists graduating each semester.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

The Applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (*e.g.*, internships, residencies, etc.).

Medical Care, PLLC works closely with East Tennessee State University in medical student rotations and nurse practitioners. The practice also works with King College and Milligan College in rotating and job shadowing nursing students.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

The Applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and applicable Medicare requirements.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure: *Tennessee Department of Health*

Accreditation: *American College of Radiology*

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Not applicable.

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Not applicable.

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Not applicable.

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Not applicable.

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

If approved, Medical Care Imaging, LLC will submit all information required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Attached as requested.

DEVELOPMENT SCHEDULE

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.

Completed as requested and attached as Project Completion Forecast Chart

2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph,* please state below any request for an extended schedule and document the "good cause" for such an extension.

Not applicable.

ATTACHMENT A.3.

FILED

COPY

Tennessee Articles of Organization a Professional Limited Liability Company

This company is organized under the Tennessee Revised Limited Liability Company Act, more specifically, Tenn. Code Ann. §48-249-1101 et seq.

1. The name of the Professional Limited Liability Company is: Medical Care, PLLC.
2. The name and address of the Professional Limited Liability Company's initial registered office in Tennessee is: Rodney S. Klein, Esq., Klein & Associates, 110 Corporate Drive, Suite 150, Johnson City, TN in Washington County, Tennessee.
3. Number of members at the time of organization is 3.
4. The Professional Limited Liability Company will be member managed.
5. This document is to be effective as of the date of filing.
6. The complete address of the Professional Limited Liability Company's principal office is: 401 E. Main St., Johnson City, TN 37601 in Washington County.
7. The Period of Duration is perpetual.
8. The purpose of the Professional Limited Liability Company is to render medical services and other ancillary services.
9. The Professional Limited Liability Company has one or more qualified members and no disqualified members.

December 10, 2008
Signature Date

Jeffrey Hopland
Signature *(manager or member authorized to sign by the Professional Limited Liability Company)*

Member
Signer's Capacity

Jeffrey Hopland
Name

5410.0388

STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

STEVEN HOPLAND
401 EAST MAIN STREET
JOHNSON CITY, TN 37601

March 7, 2013

Request Type: Certificate of Existence/Authorization
Request #: 0091432

Issuance Date: 03/07/2013
Copies Requested: 1

Document Receipt

Receipt # : 941710 — Filing Fee: $22.25

Payment-Credit Card - TennesseeAnytime Online Payment #: 149232000 — $22.25

Regarding:	**MEDICAL CARE, PLLC**		
Filing Type:	Limited Liability Company - Domestic	Control # :	592623
Formation/Qualification Date:	12/22/2008	Date Formed:	12/22/2008
Status:	Active	Formation Locale:	TENNESSEE
Duration Term:	Perpetual	Inactive Date:	
Business County:	WASHINGTON COUNTY		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

MEDICAL CARE, PLLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent corporation annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 002625715

ATTACHMENT A.4.

The Applicant, Medical Care, PLLC, is a member managed Tennessee medical professional limited liability company. The existing members of Medical Care, PLLC and each of their respective percentage ownership interests in the company are as follows:

Member	Percentage Interest
Arnold Hopland, M.D.	33.33%
Jeff Hopland, M.D.	33.33%
Kenny Hopland, M.D.	33.33%

Neither the Applicant nor any of its owners have a financial interest in any other "health care institution" as defined in Tennessee Code Annotated §68-11-1602 in Tennessee.

The Applicant is managed by Pine Palms Management, LLC, a Tennessee limited liability company. The current CEO is Steve Hopland. The members of Pine Palms Management, LLC and each of their respective percentage ownership interests in the company are as follows:

Member	Percentage Interest
Arnold Hopland, M.D.	20%
Steve Hopland	20%
Jeff Hopland, M.D.	20%
Jenny Whaley	20%
Kenny Hopland, M.D.	20%

ATTACHMENT A.5.

MANAGEMENT SERVICES AGREEMENT

THIS MANAGEMENT SERVICES AGREEMENT (this "Agreement") is made and entered into as of March 1, 2013, by and between **Pine Palms Management, LLC** a Tennessee limited liability company (the "Manager") and **Medical Care, PLLC**, a Tennessee limited liability company (the "Owner"), which intends to owns and operates an magnetic resonance imaging (MRI) at Medical Care, PLLC located at 1500 West Elk Ave, Elizabethton, Tennessee (the "MRI"). This agreement is contingent on the successful approval of certificate of need to establish MRI services. If such approvals are not received before December 31, 2013 this agreement is null and void with no further obligation to either party.

I. GENERAL

1. The Owner hereby retains the Manager for the purpose of rendering management, administration and purchasing services and support, and all other management support needed for operation, and in the best interest, of the MRI on the basis hereafter set forth, consistent with the mission of Owner and subject to the policies established by the Owner, which policies shall be consistent with applicable state and federal law.

2. The Manager shall perform all of the services described in Article II and Article III hereof for the account of and as agent of the Owner. All such services shall be rendered using the Manager's best efforts and subject to the control of the Owner, which shall have final authority in all matters relating to the MRI's operations.

3. The Owner hereby appoints the Manager its attorney-in-fact with full power on its behalf and in its name, or in the name of the MRI, to enter into contracts relating to the affairs of the MRI; provided, however, the Manager shall not incur any obligation for repairs, equipment, additions or betterments if to do so would exceed budgeted expenditure levels (whether capital or operating) without first requesting the consent of Owner. In the event that Owner does not respond in writing to Manager's expenditure request within five (5) days of receipt thereof, then such expenditure shall be deemed approved by Owner.

4. Except in the event of the merger or consolidation of the Manager, or the sale by the Manager of substantially all of its assets, the Manager shall not assign this Agreement, other than to a subsidiary corporation or other entity controlled by or under common control with the Manager, without the written consent of the Owner, which consent shall not be unreasonably withheld.

5 The term of this Agreement shall commence as of the date set forth in the preamble of this Agreement and shall continue for a term of five (5) years through March 1, 2018 unless this Agreement is terminated pursuant to this Article I. This Agreement shall automatically renew for additional successive terms of one (1) year each unless one party gives the other party sixty (60) days prior written notice of termination before the expiration of the then current term.

6. The Owner shall have the right to terminate this Agreement upon the Manager's material breach of this Agreement. In the event termination is for an alleged material breach by the Manager, such notice shall describe in detail the basis upon which the Owner believes such termination is justified. Upon receipt of such notice, the Manager shall have ninety (90) days (or thirty (30) days in the event that the Manager's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under this Agreement, and upon such cure being effected, the Owner's rights to terminate shall cease and this Agreement will continue in full force and effect. Furthermore, if the Manager has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental agency) to act within such period, then the Manager shall have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Owner's election to terminate.

7. The Manager shall have the right to terminate this Agreement upon the Owner's material breach of this Agreement. In the event termination is for an alleged material breach by the Owner, such notice shall describe in detail the basis upon which the Manager believes such termination is justified. Upon receipt of such notice, the Owner shall have ninety (90) days (or thirty (30) days in the event that the Owner's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under this Agreement, and upon such cure being effected, the Manager's rights to terminate shall cease and this Agreement will continue in full force and effect. Furthermore, if the Owner has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental agency) to act within such period, then the Owner shall

have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Manager's election to terminate. Notwithstanding the foregoing, Manager shall have the right to suspend the provision of services under this Agreement in the event that Owner fails to pay any of the compensation payable pursuant to Article IV as and when due.

8. If either party shall appoint or consent to the appointment of a receiver, trustee or liquidator of such party or of all or a substantial part of its assets, file a voluntary petition in bankruptcy, make a general assignment for the benefit of creditors, file a petition or an answer seeking reorganization or arrangements with creditors or to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating such party bankrupt or insolvent, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) days, then, in case of any such event, the term of this Agreement shall terminate, at the option of the non-defaulting party, upon written notice to the other party.

9. In addition to the foregoing, after the first anniversary of the effective date of this Agreement, either party may terminate this Agreement, without cause, upon not less than ninety (90) days prior written notice.

II. MANAGEMENT SERVICES

1. Subject to the provisions of Article I, the Manager will render all services, direction, advice, supervision and assistance in the operation of the MRI as necessary, including, but in no way limited to, the following:

A. Obtain and maintain the accreditation and state licensing of the MRI with the proper agencies and insurance companies including ACR or equivalent.

B. Hiring, supervising, directing, leasing and discharging, on behalf of the Owner, all personnel performing services at the MRI including the administrator of the MRI (the "Administrator"), as needed. All MRI personnel shall be employees of the Manager.

C. Negotiating fee payment methods, in coordination with the Owner, including Medicare reimbursement, with the appropriate third party payors and state and federal agencies;

D. Establishing staffing schedules, wage structures and personnel policies for all personnel;

E. Determining and setting patient charges for MRI services;

F. Providing policies and operating procedures to all departments;

G. Providing for the purchase, lease or disposition by the Owner of all supplies and equipment including information systems hardware and software used in the operation of the MRI;

I. Directing the day-to-day operations of the MRI to insure the operations are conducted in a businesslike manner consistent with the policies adopted by Owner from time to time;

J. Performing all management and non-medical oversight responsibilities for the Owner;

K. Negotiating or retaining on behalf of the Owner contractual relationships for radiologist services, and other professional services as appropriate;

III. ACCOUNTING AND BOOKKEEPING SERVICES

1. The Manager agrees to provide or cause to be provided the following accounting and bookkeeping services for the Owner in the operation of the MRI:

A. Receipt for and deposit of all funds received from the operation of the MRI and supervise the disbursement of such funds for the operating expenses of the MRI.

B. Maintain the books of account, including all journals and ledgers, check register and payroll records;

C. Post all patient and other charges, including necessary analysis and corrections;

D. Establish adequate receivables, credit and collection policies and procedures;

E. Process vendors' invoices and other accounts payable;

F. Prepare or contract for processing payroll checks from time sheet summaries prepared under the Manager's supervision;

G. Prepare payroll and supervise preparation of the Owner's tax returns

H. Prepare monthly bank reconciliations;

I. Prepare monthly profit and loss statements, the format of which shall be compatible with the information systems of the Owner;

J. Establish patient billing procedures;

K. Conduct monthly meetings with the Owner's personnel, either telephonically or on-site as required; and

L. Handle patient complaints.

The Manager shall be permitted to contract for these services with an independent accounting firm or other qualified provider, provided that any expenses incurred for such outside services shall be considered to be part of the fee set forth in Article IV below.

IV. FEES FOR SERVICES AND REIMBURSABLE EXPENSES

As compensation for performing the management services required hereunder, Owner shall pay to Manager a management fee of 15% of gross collections which include the management, billing & computer support services, In addition, Manager shall be reimbursed on a monthly basis for its direct expenses incurred in connection with the management of the MRI including but not limited to (i)personnel required for daily operations , (ii) supplies and inventory (iii) equipment, maintenance and repairs (iv) Rents (v)Manager's reasonable out-of-pocket expenses; (vi) legal fees, accounting, and other professional fees incurred by Manager on behalf of Owner, and (vii) other direct expenses incurred by Manager on behalf of Owner. Manager shall submit, as requested by Owner from time to time, appropriate written documentation supporting such expenses.

Owner hereby grants to Manager the right to pay to Manager all fees and reimbursable expenses hereunder from funds received from the operation of the MRI.

V. INSURANCE

During the term of this Agreement, Owner shall, at its sole cost and expense, obtain and maintain with commercial carriers acceptable to Manager appropriate professional, casualty and comprehensive general liability insurance covering the Owner and its personnel in such amounts, on such basis and upon such terms and conditions as Owner and Manager deem appropriate.

The casualty and comprehensive general liability insurance shall insure against loss of or physical damage to the MRI and the furniture, fixtures and equipment therein, under standard all-risk coverage (including but not limited to fire, smoke, lightening, wind storm, explosion, aircraft or vehicle damage, riot, civil commotion, vandalism and malicious mischief) and shall also include damage due to flood and earthquake unless waived by Manager.

Manager shall be named an additional insured under all insurance policies procured by Owner hereunder. The right of Manager to invoke the protection of such policies shall be severable from and independent of the Owner's rights, and these policies shall not be terminable or non-renewable except upon thirty (30) days' written notice to Manager. No later than thirty (30) days following the execution of this Agreement and thirty (30) days following the end of each policy year, Owner shall give to Manager a copy of the endorsements naming Manager an additional insured. Such insurance policies shall contain endorsements which reflect the primary liability of the Owner's insurance carrier for all covered losses provided for herein, notwithstanding any insurance which may be maintained by Manager or any affiliate of Manager. Owner hereby waives any right of contribution with respect to the loss covered under such policies (or with respect to deductibles thereunder) against Manager or any of Manager's insurance carriers.

VI. INDEPENDENT CONTRACTORS

The relationship created hereby is that of an agent (Manager) contracting with a principal (Owner) as independent contractors. Neither of the parties hereto, nor their employees or agents, shall be construed to be the agent, employee, partner or representative of the other party, except as may be expressly provided for herein to the contrary.

VII. CONFIDENTIAL INFORMATION

As used in this Agreement, the term confidential information (the "Confidential Information") shall include the following: (i) all documents and other materials, including but not limited to, all memoranda, clinical manuals, handbooks, production books, educational material and audio or visual recordings, which contain information relating to the operation of the MRI or its programs (excluding written materials distributed to patients in the operation of the MRI as promotion for the MRI), (ii) all methods, techniques and procedures utilized in providing services to patients in the MRI not readily available through sources in the public domain, and (iii) all trademarks, trade names, service marks, or protected software of Manager and their related data files.

The Owner acknowledges and agrees that the Confidential Information is owned by the Manager and has been disclosed to it in confidence and with the understanding that it constitutes valuable business information developed by the Manager at great expenditure of time, effort and money. The Owner agrees that it shall not, without the express prior written consent of the Manager, use the Confidential Information for any purpose other than the performance of this Agreement. The Owner further agrees to keep strictly confidential and hold in trust all Confidential Information and not disclose or reveal such information to any third party without the express prior consent of the Manager.

Upon termination of this Agreement by either party for any reason whatsoever, the Owner shall forthwith return to the Manager all material constituting or containing Confidential Information and the Owner shall not thereafter use, appropriate, or reproduce such information or disclose such information to any third party.

The provisions of this Article VIII shall survive any termination or expiration of this Agreement. Manager shall have the right to use any Confidential Information and any technical or business expertise obtained during the course of its engagement hereunder in connection with its management of any other facility.

VIII. NOTICES

All notices permitted or required by this Agreement shall be deemed given when in writing and delivered personally via overnight courier or deposited in the United States mail, postage prepaid, return receipt requested, addressed to the other party at the address set forth below or such other address as the party may designate in writing:

To the Owner: Medical Care, PLLC
1500 West Elk Ave
Elizabethton, Tennessee 37643

To the Manager: Pine Palms Management, LLC
401 East Main Street
Johnson City, Tennessee 37601

IX. INDEMNIFICATION

1. Owner agrees to indemnify and hold harmless Manager, its affiliates and shareholders and their respective shareholders, directors, officers, employees and agents (collectively, a "Manager Indemnified Party") from and against any and all losses, claims, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses related to the defense of any claims) (a "Loss"), which may be asserted against any of the Manager Indemnified Parties or for which they may now or hereafter become subject arising in connection with the activities of the MRI, including without limitation matters relating to: (i) alleged or actual failure by the governing body, board of directors and/or similar body of Owner to perform any of its duties under this Agreement; (ii) any pending or threatened medical malpractice or other tort claims asserted against Manager relating to the MRI; (iii) any action against Manager brought by any of the MRI's current or former employees or medical staff members; (iv) any act or omission by any MRI employee, medical staff member or other personnel; and (v) any violation of any requirement applicable to the MRI under any federal, state or local environmental, hazardous waste or similar law or regulation; provided that such Loss (a) has not been caused by the gross negligence, willful misconduct or illegal conduct of Manager or the Manager Indemnified Party seeking indemnification pursuant to this Agreement or (b) is not related to a breach by Manager or any of its contractual obligations to Owner arising under this Agreement.

2. Manager agrees to indemnify and hold harmless the Owner and its members, partners, or shareholders (as appropriate), its directors or governors (as appropriate), and its officers, employees and agents (collectively, an "Owner Indemnified Party") from and against all Loss which may be asserted against any Owner Indemnified Party as a result of the gross negligence, willful misconduct or illegal conduct of Manager or a material breach of Manager's obligations under this Agreement in connection with the performance by Manager of its duties hereunder; provided that such Loss has not been caused by the gross negligence, willful misconduct or illegal conduct of the Owner or the Owner Indemnified Party seeking indemnification pursuant to this Agreement.

X. MISCELLANEOUS

1. This Agreement shall be construed to be in accordance with any and all federal and state laws, including laws relating to Medicare, TennCare, Medicaid, and other third party payers. In the event there is a change in such laws, whether by statute, regulation, agency or judicial decision, that has any material effect on any term of this Agreement, or in the event that counsel to one party determines that any term of this Agreement poses a risk of violating such laws, then the applicable term(s) of this Agreement shall be subject to renegotiation and either party may request renegotiation of the affected term or terms of this Agreement, upon written notice to the other party, to remedy such condition. In the interim, the parties shall perform their obligations hereunder in full compliance with applicable law.

The parties expressly recognize that upon request for renegotiation, each party has a duty and obligation to the other only to renegotiate the affected term(s) in good faith and, further, the parties expressly agree that their consent to proposals submitted by the other party during renegotiation efforts shall not be unreasonably withheld.

Should the parties be unable to renegotiate the term or terms so affected so as to bring such term or terms into compliance with the statute, regulation or judicial opinion that rendered same unlawful or unenforceable within thirty (30) days of the date on which notice of a desired renegotiation is given, then either party shall be entitled, after the expiration of said thirty (30) day period, to terminate this Agreement upon sixty (60) additional days written notice to the other party.

2. Article headings are for convenience of reference only and shall not be used to construe the meaning of any provision of this Agreement.

3. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one Agreement.

4. Should any part of this Agreement be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity and enforceability of the remaining portions.

5. Each individual signing this Agreement warrants that such execution has been duly authorized by the party for which he is signing. The execution and performance of this Agreement by each party has been duly authorized by all applicable laws and regulations and all necessary corporate action, and this Agreement constitutes the valid and enforceable obligation of each party in accordance with its terms.

6. This Agreement shall be construed in accordance with the laws of the State of Tennessee.

7. This Agreement may not be modified except in writing executed by the party to be charged.

8. This Agreement constitutes the entire Agreement of the parties hereto and supersedes all prior agreements and representations with respect to the subject matter hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first above written.

MANAGER:

PINE PALMS MANGEMENT, LLC

By: _____
Title: CEO

OWNER:

MEDICAL CARE, PLLC

By: _____
Title: _____

ATTACHMENT A.6.

Option to Lease

Pine Palms Management, LLC herby commits to lease Medical Care, PLLC space;

Location:	1500 West Elk Ave, Elizabethton, TN 37643
Details:	Approximately 674 Square Feet , 1st floor,
	adjacent to existing Medical Care, PLLC radiology department
Use:	Magnetic Resonance Imaging (MRI)

Pine Palms Management commits to a lease674 square feet of space for 5 years with option for additional term of 5 years. The lease will commence following occupancy of space. Lease terms will be $35.00 PSF or $1,965.83 monthly payable on the 1st of each month. This option is valid for 6 period of months or until executed lease is negotiated.

This option is contingent on Medical Care, PLLC successful approval of Certificate of Need (CON) for MRI services. If CON is not received within 6 months from initial date, one additional 6 month extension of option to lease is available at Medical Care, PLLC written request and additional fee (nonrefundable) of $5,000.

Signed _____ 2-26-13

Steven Hopland, CEO — Date

Pine Palms Management, LLC

Signed _____ 2-26-13

Kenneth Hopland, MD — Date

Medical Care, PLLC

ATTACHMENT A.13.

Section A, Applicant Profile

13. Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.

The TennCare MCOs operating in the proposed service area (Carter, Washington, Sullivan, Johnson and Unicoi Counties) are BlueCare, TennCare Select and UnitedHealthcare Community Plan.

Will this project involve the treatment of TennCare participants?

Yes.

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

The Applicant has contracts with BlueCare, TennCare Select and UnitedHealthcare Community Plan.

ATTACHMENT B.I.

MOUNTAIN STATES
HEALTH ALLIANCE

09/12/2012

To our fellow physicians:

In order to best serve our patients and effectively articulate our policy change implemented September 3rd, we are reaching out asking for your continued support. Now that we have established pre-payment requirements for non-emergent scheduled procedures, we recognize the need to allow ample time for our patients to secure financial clearance. Therefore, we are requesting that non-emergent cases be scheduled at least 3 business days in advance, effective for procedures scheduled on or after Monday September 24th.

We appreciate your support as we work through implementation of these new processes. We understand this type of change may be a bit tenuous at the inception, but it is an important initiative towards sustaining financial viability and ensuring our facilities can continue to meet the healthcare needs of our communities. Other systems within our region are adopting similar practices.

Please remember that an appeals process is in place for exceptional cases. If the ordering physician wishes to initiate an appeal, he or she may contact the Chief Medical Officer of the facility in question. Thank you for your understanding and cooperation as we work to create an environment that is sustainable, both for patients and providers. If you have questions, please contact one of the MSHA officials listed below.

Sincerely,

Morris H. Seligman, MD, FACP
SVP/Chief Medical Officer,
Mountain States Health Alliance
SeligmanMH@msha.com | 423-302-3373

Douglas Edema, MD
President/Chief Executive Officer
Mountain States Medical Group
EdemaDA@msha.com | 423-915-5195

Jim Paskert, MD
VP/Chief Medical Officer
MSHA Washington County, TN Operations
PaskertJP@msha.com | 423-431-1061

Clay Runnels, MD
AVP/Medical Director of Emergency Svcs
Mountain States Health Alliance
RunnelsCW@msha.com | 423-431-1983

Frank Lauro, DO, FACC, FACOI
VP/Chief Medical Officer,
Indian Path Medical Center / Mountain States Medical Group
LauroFJ@msha.com | 423-202-0256

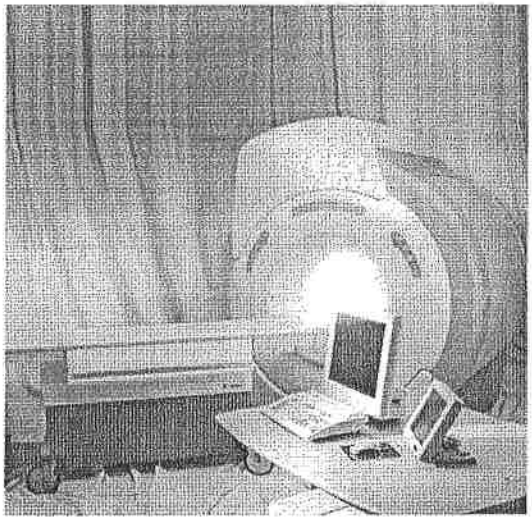
Hughes Melton, MD
VP/Chief Medical Officer,
MSHA Virginia Operations
MeltonSH@msha.com | 276-971-6302

ATTACHMENT B.II.E.1.a.1.

OiService®

OXFORD INSTRUMENTS
The Business of Science®

Medical Care PLLC
1500 West Elk Avenue
Elizabethton, TN 37643



Reconditioned GE Signa 1.5T 12x EXCITE 8-Channel MRI Scanner
Equipment Quotation

Prepared By:
Will Hengemuhle, Jr.
December 17, 2012
843.568.9865 Cell

OiService®

OXFORD INSTRUMENTS
The Business of Science®

AGREEMENT NUMBER: 121712-WH
DATE: December 17, 2012

Reconditioned GE Signa 1.5T 12x Excite 8-Channel MRI

Hardware Summary

- CX-K4 1.5T Actively Shielded Short Bore Magnet
- 1.5T Excite HD EchoSpeed Plus 8-Channel Electronics with Phased Array
- ACGD Plus Gradient Driver 33 mT/m, Slew Rate 120
- Excite Digital RF System
- Detachable Patient Table
- HP Linux Dual Processor Workstation/Operator Console w/ Color LCD Monitor
- Vector 400 Recon Module (Vector 800 available as an option)

Coils

- 8-Channel CTL Spine Array Coil
- 8-Channel Body Coil
- 8-Channel Neurovascular Array
- 4-Channel Torso Array Coil
- 4-Channel Shoulder Array Coil
- Quad Extremity Coil w/ Chimney
- General Purpose Flex Coil (x2)
- Dual TMJ Coil and Dual Array Adaptor
- Breast Coil

12x Software and Options Summary

- EXCITE ScanTools 12x Software
- Spin Echo, Fast Spin Echo
- Gradient Echo, Fast Gradient Echo
- Time of Flight, Phase Contrast
- Echo Planar Pulse Sequence
- FuncTool, ClariView
- ConnectPro (Modality Worklist)
- Performed Procedure Step
- Multi Planar Volume Reformat
- Interactive Vascular Imaging

Advanced Neuro Imaging – EchoPlus, 3D Fiesta, Fiesta—C, Asset

Advanced Body and Breast Imaging – Asset, Firm, Fame, Special, 2D Fat Sat Fiesta, LAVA

Vascular Imaging – SmartPrep, SmartStep, Elliptic Centric, FTMRA

Cardiact Imaging – iDrivePro Plus, FastCine, FastCard, 2D Fiesta, 3D Fat Sat Fiesta

Other Items

- Main Disconnect Panel
- Note: Installation of the above by licensed contractors

****SUBJECT TO AVAILABILITY****

OiService®

OXFORD INSTRUMENTS
The Business of Science®

PURCHASE AND SALE AGREEMENT
(EQUIPMENT)

Oxford Instruments Service LLC ("OI SERVICE"), located at 1027 SW 30th Avenue, Deerfield Beach, FL 33442, hereby agrees to sell; and **Medical Care PLLC ("PURCHASER"),** located at 1500 West Elk Avenue Elizabethton, TN 37643, hereby agrees to purchase the equipment described below ("Equipment") in accordance with the terms and conditions forth below in this Agreement and the standard terms and conditions set forth in Exhibit A, attached hereto and incorporated to this Agreement by reference:

PURCHASE PRICE: Three Hundred and Ninety-Nine Thousand Dollars, ($399,000.00) ("Purchase Price"). The Purchase Price and any other amounts payable under this Agreement shall be paid in U.S. Dollars by the wire transfer of immediately available funds to bank account directed by OI SERVICE.

EXECUTION OF AGREEMENT AND DEPOSIT BY PURCHASER: PURCHASER shall return an executed Agreement to OI SERVICE on or before March 1, 2013, along with a deposit of $119,700.00 (30% of Purchase Price) via wire transfer of immediately available funds to a bank account directed by OI SERVICE. If PURCHASER fails to execute this Agreement and pay the deposit prior to such date, the terms and conditions set forth in this Agreement shall be null and void.

PAYMENT TERMS: The Purchase Price shall be paid as follows: (i) 30% of the Purchase Price upon the execution of this Agreement; (ii) 60% upon written notice of shipment to PURCHASER's site and prior to delivery of the Equipment to the PURCHASER'S site; and (iii) 10% upon the first use of the Equipment, but no later than 30 days after the delivery of the Equipment.

REFURBISHMENT: Refurbishing of Equipment includes inspecting all mechanical parts and adjusting or replacing parts if necessary, along with professional cleaning and painting to look like new.

LIMITED WARRANTY: The limited warranty provided by OI SERVICE shall be governed pursuant to the terms and conditions set forth on Exhibit "A" attached hereto and made a part hereof.

Every attempt has been made to assure complete and accurate system specifications to the best of our ability.

INSTALLATION, TURNOVER AND ON-SITE APPLICATIONS TRAINING: The installation and turnover of the Equipment, along with applications training shall be governed pursuant to the terms and conditions set forth on Exhibit "A" attached hereto and made a part hereof.

DELIVERY DATE: The Equipment shall be de-installed and delivered on or before June 1, 2013("Delivery Date") at 1500 West Elk Avenue Elizabethton, TN 37643 . OI SERVICE shall pay all transportation costs.

ACCEPTANCE OF TERMS AND CONDITIONS: OI SERVICE and PURCHASER have carefully read the terms and conditions of this Agreement and its Standard Terms and Conditions. The undersigned are duly authorized to execute this Agreement on behalf PURCHASER and OI SERVICE.

"OI SERVICE"

Oxford Instruments Service LLC

BY: _____
Jeffrey D. Fall

INT:_____
DATE:

"PURCHASER"

Medical Care PLLC TAX ID No.:

BY: _____
Purchaser Signature

INT:_____
DATE:

EXHIBIT A
STANDARD TERMS AND CONDITION

1. **INCORPORATION OF ADDITIONAL TERMS AND CONDITIONS:** This Exhibit is an integral part of OI SERVICE's offer to sell the Equipment to PURCHASER. By signing the Agreement and the Exhibit and returning it to OI SERVICE, PURCHASER hereby accepts all of the terms and conditions set forth in this Agreement, including, but limited to the terms set forth in this and any other Exhibit.

2. **DEFAULT:**

(a) If OI SERVICE fails to deliver the Equipment within (45) days after the Delivery Date, then PURCHASER shall have the right to cancel this Agreement and receive a full refund of any and all funds paid to OI SERVICE, including, but limited to all deposits and prepayments. The aforementioned refund shall be PURCHASER's sole and exclusive remedy.

(b) If PURCHASER fails to comply with the payment terms described on the first page of this Agreement, and such non-payment continues for a period of five (5) after such payment due date, then in addition to any and all rights and remedies available to OI SERVICE at law or equity, OI SERVICE shall have the right to cancel this Agreement and retain any and all funds paid to OI SERVICE, including, but limited to all deposits and prepayments.

(c) In the event OI SERVICE agrees to accept multiple payments to satisfy the Purchase Price which shall be paid over a period of time, PURCHASER hereby grants OI SERVICE a purchase money security interest under the UCC in all Equipment to secure full payment for such goods is received. PURCHASER shall execute any documents required by OI SERVICE to perfect such security interest in the Equipment, and where permitted PURCHASER hereby authorizes OI SERVICE to sign and file the same without PURCHASER's signature. PURCHASER agrees to pay any and all expenses related to the preparation and filing of such documents.

3. **TRANSFER OF TITLE:** Upon OI SERVICE's' receipt of the full Purchase Price, OI SERVICE shall assign, transfer and convey all of its right, title and interest in the Equipment to PURCHASER, free and clear of all liens and encumbrances.

4. **INSTALLATION, TURNOVER AND ON-SITE APPLICATIONS TRAINING:**

(a) OI SERVICE shall provide PURCHASER with site planning assistance including preliminary/final room drawings. OI SERVICE shall only perform commercially normal installation. There will be no special rigging requirements such as the use of cranes. The PURCHASER agrees to pay upon receipt of invoice from OI SERVICE any amount above $7,500 for rigging of the Equipment into the site of installation.

(b) PURCHASER shall be responsible to prepare the site in accordance with the site plan and the specifications of the Original Equipment Manufacturer (OEM). All applicable, licenses and/or permits shall be the responsibility of the PURCHASER.

(c) OI SERVICE shall provide 7-days on-site applications training. The training schedule is generally 4-5 days following the turnover of the Equipment, and 2-3 days follow up. Training is approved for CEU's.

(d) The following Service shall <u>not</u> be provided by OI SERVICE:

(i) RF Room and Shielding

(ii) Installation of air conditioning units, water chillers, and electrical panels and related equipment and environmental which shall be performed by licensed contractors hired by PURCHASER.

(iii) Site modifications and renovations to the installation site as would be required by Original Equipment Manufacturer (OEM) specifications.

(e) The procedure for the installation and turnover of the Equipment, along with on-site applications training is as follow:

(i) Upon the delivery of the Equipment and upon PURCHASER's completion of site preparation, OI SERVICE shall commence installation the Equipment (in accordance with the provision set forth in paragraphs (a) and (b) above); provided that if Purchaser delays the installation of the Equipment or the site has not been properly prepared by Purchaser for installation within 5 business days of the Delivery Date, then the installation and turnover of the Equipment shall be deemed accepted. Further, shall pay OI SERVICE a storage fee in the amount of $2,000.00 per month (plus the cost of any cryogens required to keep the magnet cold while in storage), and such fees shall be due and payable prior to the delivery and installation of the Equipment at the site.

(ii) OI SERVICE shall schedule and provide Purchaser's employees with application training for the Equipment(in accordance with the provision set forth in paragraph (c) above) upon completion of the installation of the Equipment; provided however, if Purchaser delays the application training by more than 5 business days, then the installation and turnover of the Equipment shall be deemed accepted.

(iii) Upon completion of the installation of the Equipment and the applications training, OI SERVICE shall provide Purchaser with a Certificate of Acceptance which shall provide that: (A) the Equipment has been properly installed and the Equipment meets or exceeds the original specifications of the original equipment manufacturer, and (B) the application training has been completed.

(iv) Purchaser shall have 5 business days from the receipt of the Certificate of Acceptance to provide OI SERVICE with either: (A) written acceptance to the installation and turnover of the Equipment; or (B) provide OI SERVICE with written notice which describes any issues relating to the Equipment's conditions or specifications, the installation of the Equipment or the application training.

(v) If Purchaser fails to provide OI SERVICE with a written response to the Certificate of Acceptance in accordance with subparagraph (iv) above, then the installation and turnover of the Equipment shall be deemed accepted.

5. **RISK OF LOSS:** The risk of loss from any damages or casualty to the Equipment shall passes from OI SERVICE to PURCHASER when the Equipment is duly delivered to the transportation carrier or the Equipment is picked up by the transportation carrier.

6. **LIMITED WARRANTY**:

(a) Subject to the provisions set forth below, OI SERVICE shall provide a limited warranty for a 12 month period commencing on the earlier of: (i) acceptance of the Equipment by PURCHASER (in accordance with the terms set forth on Exhibit "A"), or (ii) first clinical use and billing of patient ("Warranty Period"). The warranty coverage period is M-F, 8am—5pm, excluding holidays.

(b) OI SERVICE warrants that the Equipment is free from defects in material or workmanship under normal use and service. There shall be no warranty on consumables. The limited warranty shall cover all parts and labor (surface coils and cryogens – which shall not exceed 1000 liters).

(c) Any Equipment found to be defective during the "Warranty Period shall be repaired or replaced free of charge, provided that PURCHASER satisfies all of the following conditions: (i) PURCHASER gives written notice of the defect (with reasonable relevant information) to OI SERVICE as soon as reasonably practicable and within the Warranty Period; (ii) the Equipment has been used solely for its proper purpose and in accordance with the operating instructions specified by the original equipment manufacturer (including, but not limited to meet or exceed the proper power requirements in accordance with the specifications of the original equipment manufacturer and all HVAC requirements); (iii) the defect has not been caused by fire, accident, misuse, neglect, incorrect installation by PURCHASER or its customers, agents or servants, (iv) there has been no unauthorized alteration, repair or maintenance or the use of sub-standard consumables; (v) the defect has not arisen from any design, specification, component or material supplied by or on behalf of PURCHASER; (vi) no part of the Equipment has been replaced with a part not supplied or

approved by OI SERVICE; ((vii) all repairs to the Equipment have been made by personal of OI SERVICE or approved by OI SERVICE; (viii) PURCHASER has made all payments due and owing to OI SERVICE.

In the event PURCHASER fails to meet the requirements set forth in sub-paragraph (c)(ii) above, OI SERVICE shall have the right to impose additional charges to PURCHASER or void the limited warranty set forth herein, as provided by OI SERVICE in its sole discretion.

(d) PURCHASER shall be liable for any costs incurred by OI SERVICE in responding to claims caused by operator error or incorrect application or other default of PURCHASER or other third party;

(e) PURCHASER shall pay the costs of all consumables.

(f) OI SERVICE, at its sole discretion, shall determine whether to replace or repair the Equipment.

(g) If a part fails within this Warranty Period and is replaced or repaired, then the new part will have a warranty period equal to the remaining period of the part that failed.

(h) OI SERVICE, at is option and sole discretion, may repair the Equipment at the site of PURCHASER or direct PURCHASER to have the Equipment returned to OI SERVICE's premises. If repairs are made at the location of PURCHASER, OI SERVICE will not charge for the cost of materials or labor but will, at its discretion, charge travelling and subsistence expenses incurred by OI SERVICE's representatives; and

(i) PURCHASER shall accord OI SERVICE and its representatives or agents sufficient and timely access to the Equipment to enable its staff to inspect and adjust, repair, remove or replace the agents sufficient and timely access to the Equipment to enable its staff to inspect and adjust, repair, remove or replace the Equipment; and

(j) THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, DESCRIPTION AND FITNESS FOR PARTICULAR PURPOSE.

7. LIMITATION OF WARRANTIES AND LIABILITY, HOLD HARMLESS:

(a) PURCHASER ACKNOWLEDGES THAT OI SERVICE DID NOT MANUFACTURE THE EQUIPMENT, AND THAT EXCEPT AS SET FORTH HEREIN, OI SERVICE MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE, WITH RESPECT TO THE EQUIPMENT. THIS AGREEMENT STATES OI SERVICE'S ENTIRE OBLIGATION WITH RESPECT TO THIS TRANSACTION. EXCEPT AS SET FORTH HERIN, OI SERVICE PROVIDES NO WARRANTY OF OPERABILITY AND WILL HAVE NO LIABILITY FOR ANY FAILURE OF THE EQUIPMENT AFTER PURCHASER OR ITS AGENTS TAKE TITLE AND BEGIN DEINSTALLATION. IN NO EVENT WILL OI SERVICEOR ITS AGENTS BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES, INCLUDING LOSS OF USE, PROJECTED PROFITS, OR OTHER FINANCIAL LOSSES DERIVING FROM THE SALE OR USE OF THE ABOVE MENTIONED EQUIPMENT, NOR SHALL OI SERVICEOR ITS AGENTS BE LIABLE FOR ANY DAMAGES FOR BODILY INJURY.

(b) PURCHASER AGREES TO INDEMNIFY, DEFEND, AND HOLD HARMLESS OI SERVICE AGAINST ANY AND ALL CLAIMS JUDGMENTS, COSTS (INCLUDING ACTUAL ATTORNEY FEES), EXPENSES, OR OTHER LOSSES TO ANY PERSON, GROUP OR ENTITY, DERIVING FROM OI SERVICE'S SERVICE. IN THE EVENT THAT THE TRANSFER IS NOT COMPLETED FOR ANY REASON, INCLUDING FORCE MAJEURE, ACTS OF WAR OR GOD, OR WITHDRAWAL OF THE EQUIPMENT FOR SALE, THE SOLE LIABILITY OF OI SERVICE SHALL BE LIMITED TO THE RETURN OF ALL MONIES ALREADY PAID TO OI SERVICE BY PURCHASER, INCLUDING DEPOSITS. PURCHASER WILL HAVE NO

OTHER REMEDY UNDER LAW FOR ANY REASON WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOSS OF USE OR DERIVATIVE PROFITS OR ANY OTHER DAMAGES.

8. **SOFTWARE.**

(a) PURCHASER acknowledges and agrees that OI SERVICE has no rights, titles, and interest in and to software relating to the Equipment, and that OI SERVICE has no right to grant any licenses thereunder. PURCHASER further acknowledges and agrees that all, rights, title and interest in such software remains with the original equipment manufacturer ("OEM").

(b) OI SERVICE make no representations and warranties to PURCHASER that the software was properly installed in the Equipment and that it will perform substantially as described in the OEM's specification for the Equipment.

(c) By executing this Agreement, the PURHASER hereby designates OI SERVICE as PURCHASER's attorney in fact, with full power and authority to act on PURCHASER's behalf with the OEM in connection with obtaining the necessary software from the OEM to operate, repair or maintain the Equipment.

9. **TAXES:** Any sales, use, property, or other taxes or regulatory fees applicable to this transaction will be in addition to the purchase price quoted, and shall be due and payable by PURCHASER. PURCHASER shall provide to OI SERVICE proof of any claimed exemption from the foregoing items.

10. **SUBCONTRACTORS:** OI SERVICE reserves the right to utilize sub-contracts for any of the required to meet its obligations under this Agreement.

11. **APPLICABLE LAW, ARBITRATION, LITIGATION, JURISDICTION, AND VENUE:**

(a) This Agreement shall be governed by and interpreted by the laws of the State of Massachusetts. Any Controversy or Claim arising out of or in relation to this Agreement, or breach thereof, shall be submitted to binding arbitration. Any such arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association, but not necessarily administered by the American Arbitration Association. The venue of any such arbitration shall be the State of Massachusetts. Any controversy will be submitted to a panel of three arbitrators. PURCHASER and OI SERVICE shall each select one arbitrator and those arbitrators shall select a third arbitrator. Any arbitrator must be a member of the Massachusetts Bar Association. The fees for the arbitrators will be levied as follows: PURCHASER and OI SERVICE will each be responsible for paying the respective fee of the arbitrator they selected. PURCHASER and OI SERVICE will each pay fifty percent (50%) of fees charged by the third arbitrator. Judgment upon the award rendered by the arbitrators may be entered and enforced by any court having jurisdiction. The prevailing party in arbitration shall be awarded all costs incurred in connection with the pursuit of its claims, including filing fees, arbitrators' fees, and reasonable attorney fees.

(b) PURCHASER hereby consents to personal jurisdiction in the State of Massachusetts and to venue in the county or federal district in which OI SERVICE maintains its headquarters.

12. **ENTIRE AGREEMENT, NON-CANCELLATION:** This Agreement (and all exhibits) represents the entire agreement between the parties, is a final expression of that agreement, is non-cancelable, and supersedes any previous oral or written agreements between the parties. Any changes must be in writing signed by both parties. This Agreement will not be binding until signed by both parties, and can be withdrawn by either party at any time, without notice, prior to signature by either party.

13. **MISCELLANEOUS PROVISIONS:**

(a) Paragraph headings used in this Agreement are of no legal effect;

(b) If any provision contained in this Agreement is determined to be invalid, illegal or otherwise unenforceable, the remaining provisions shall be fully enforceable;

(c) Any forbearance by either party from enforcing any term of this Agreement shall not constitute a waiver of any right under this Agreement, unless stated in writing;

(d) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. A copy of a signature received through telefax transmission or other electronic means (including in Adobe pdf or similar format) shall bind the party whose signature is so received as if such signature were an original;

(e) PURCHASER may not assign any of its rights or obligations under this Agreement without the prior written consent of OI SERVICE which consent shall not be unreasonably withheld;

(f) All Exhibits to this Agreement are expressly made a part of this Agreement as fully as though completely set forth in this Agreement;

OI SERVICE and PURCHASER do each hereby agree and accept the terms and conditions set forth in this Exhibit.

"OI SERVICE"

Oxford Instruments Service LLC

BY: _____
Jeffrey D. Fall

INT:_____

DATE:

"PURCHASER"

Medical Care PLLC TAX ID No.:

BY: _____
Purchaser Signature

INT:_____

DATE:

ATTACHMENT B.II.E.1.a.3.

CPT	
70551	MRI HEAD W/O CONTRAST
70552	MRI HEAD W/ CONTRAST
70553	MRI HEAD W/ & W/O CONTRAST
71550	MRI CHEST W/O CONTRAST
71551	MRI CHEST W CONTRAST
71552	MRI CHEST W & W/O CONTRAST
72141	MRI CERVICAL SPINE W/O CONTRAST
72142	MRI CERVICAL SPINE W/ CONTRAST
72146	MRI THORACIC SPINE W/O CONTRAST
72147	MRI THORACIC SPINE W/ CONTRAST
72148	MRI LUMBAR SPINE W/O CONTRAST
72149	MRI LUMBAR SPINE W/ CONTRAST
72156	MRI C SPINE W/ & W/O CONTRAST
72157	MRI T SPINE W/ & W/O CONTRAST
72158	MRI L SPINE W/ & W/O CONTRAST
72195	MRI PELVIS W/O CONTRAST
72196	MRI PELVIS W CONTRAST
72197	MRI PELVIS W & W/O CONTRAST
73218	MRI UPPER EXTREMITY W/O CONTRAST
73219	MRI UPPER EXTREMITY W CONTRAST
73220	MRI UPPER EXTREMITY W & W/O CONTRAST
73221	MRI UPPER EXTREMITY JOINT W/O CONTRAST
73222	MRI UPPER EXTREMITY JOINT W CONTRAST
73223	MRI UPPER EXTREMITY JOINT W & W/O CONTRAST
73718	MRI LOWER EXTREMITY W/O CONTRAST
73719	MRI LOWER EXTREMITY W CONTRAST
73720	MRI LOWER EXTREMITY W & W/O CONTRAST
73721	MRI LOWER EXTREMITY JOINT W/O CONTRAST
73722	MRI LOWER EXTREMITY JOINT W CONTRAST
73723	MRI LOWER EXTREMITY JOINT W & W/O CONTRAST
74181	MRI ABDOMEN W/O CONTRAST
74182	MRI ABDOMEN W CONTRAST
74183	MRI ABDOMEN W & W/O CONTRAST

ATTACHMENT B.II.E.1.a.4.

K041476

GE Healthcare Technologies
P.O. Box 414, Milwaukee, WI 53201

JUN 17 2004

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Healthcare Technologies
PO Box 414
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Manager, Regulatory Programs

Telephone: 262- 544-3894

Fax: 262- 548-4768

Date Prepared: May 28, 2004

Device Name:

GE Signa® Excite 1.5T MR System, and
GE Signa® Excite 3.0T MR System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The Signa® Excite 1.5T MR System is substantially equivalent to the currently marketed Signa® 1.5T Infinity MR system (K013636) with the main differences being a change to the receive chain architecture that includes sixteen independent receive channels, and allows for future expansion in 16 channel increments.

The Signa® Excite 3.0T MR System is substantially equivalent to the currently marketed Signa® 3.0T Infinity with Excite Technology MR system (K030874) with the main differences being a change to the receive chain architecture that includes sixteen independent receive channels, and allows for future expansion in 16 channel increments.

Device Description:

The Signa® Excite 1.5T and 3.0T Magnetic Resonance Systems are a modification to the previously cleared MR systems K013636, and K030874 which utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The Signa® Excite 1.5T and 3.0T Magnetic Resonance System features a superconducting magnet operating at either 1.5T, or 3.0T. The data acquisition system supports 1, 4, 8, 16 independent receive channels and multiple independent coil elements per channel during a single acquisition series. Additionally, the system architecture is designed for expansion in 16 channel increments. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences. Images are acquired and reconstructed using 2D and 3D Fourier transformation techniques. The system is intended for high-resolution anatomical applications, short scan times, and multinuclear spectroscopy.

Indications for Use:

The GE Signa® Excite MR system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The Signa® Excite MR system is indicated for use as a diagnostic imaging device to produce axial sagittal, coronal and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the Signa® Excite system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Comparison with Predicate Device:

The Signa® Excite 1.5T and 3.0T MR Systems are a modification of the previously cleared MR systems K013636, and K030874 with the main differences being the change to the receive chain architecture that includes sixteen independent receive channels, and allows for future expansion in 16 channel increments.

Summary of Studies:

The Signa® Excite 1.5T and 3.0T Magnetic Resonance Systems were evaluated to the appropriate NEMA performance standards as well as the IEC 60601-1 International Medical Equipment Safety standard and IEC 60061-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. The Signa® Excite 1.5T Magnetic Resonance System is comparable to the currently marketed Signa® 1.5T Infinity Magnetic Resonance System. The Signa® Excite 3.0T Magnetic Resonance System is comparable to the currently marketed Signa® 3.0T Infinity with Excite Technology Magnetic Resonance System.

Conclusion:

It is the opinion of GE that the Signa® Excite 1.5T Magnetic Resonance System is substantially equivalent to the Signa® 1.5T Infinity Magnetic Resonance System. Usage of the Signa® Excite 1.5T Magnetic Resonance System does not result in any new potential hazards.

It is the opinion of GE that the Signa® Excite 3.0T Magnetic Resonance System is substantially equivalent to the Signa® 3.0T Infinity with Excite Technology Magnetic Resonance System. Usage of the Signa® Excite 3.0T Magnetic Resonance System does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Healthcare Technologies
P.O. Box 414 W-400
MILWAUKEE WI 53201

Re: K041476
Trade/Device Name: GE Signa® Excite 1.5T MR System, and GE Signa® Excite 3.0 MR Systen
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: May 28, 2004
Received: June 3, 2004

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041476

GE Healthcare Technologies
P.O. Box 414, Milwaukee, WI 53201

STATEMENT OF INTENDED USE

510(k) Number (if known): K041476

Device Name: **GE Signa® Excite 1.5T MR System, and GE Signa® Excite 3.0T MR System**

Indications for Use

The GE Signa® Excite MR system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The Signa® Excite MR system is indicated for use as a diagnostic imaging device to produce axial sagittal, coronal and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the Signa® Excite system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

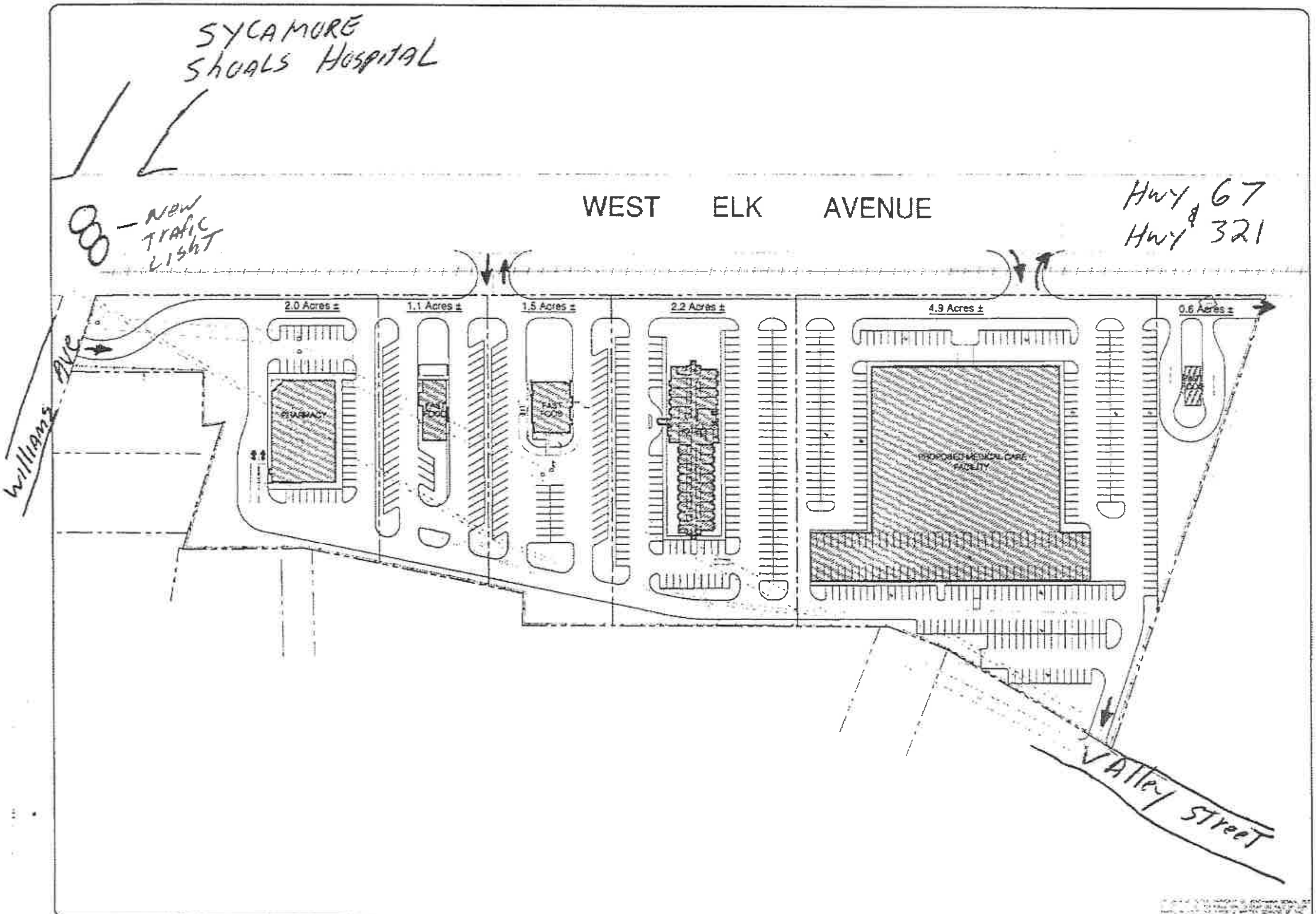
(PLEASE DO NOT WHITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041476

ATTACHMENT B.III.(A)



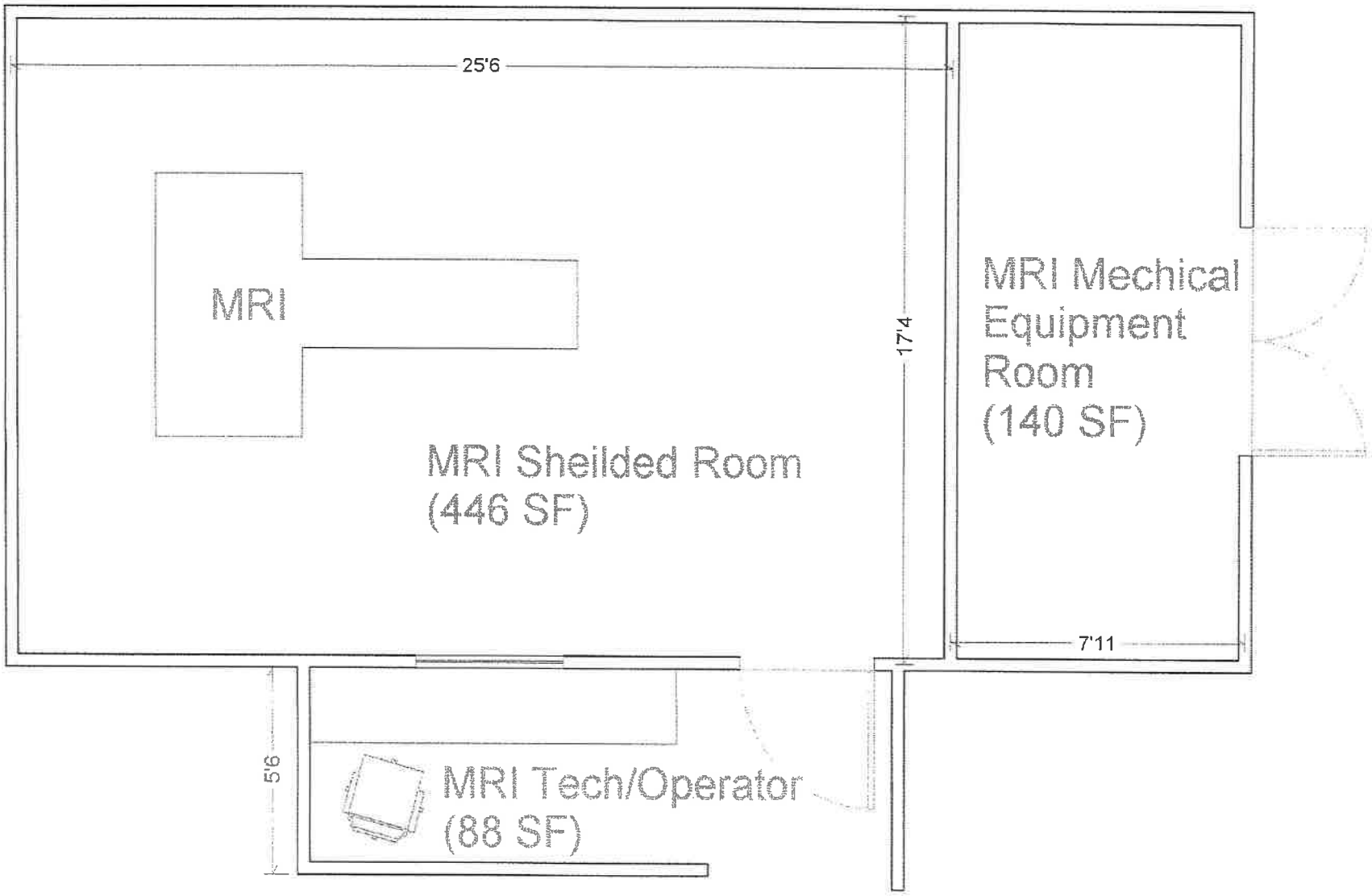
Beachmark Design, PLC
ENGINEERING & SURVEYING

PRELIMINARY MASTER PLAN
LAYOUT 4

DEVELOPMENT PLANS FOR
MEDICAL CARE
ELIZABETHTON, TENNESSEE

P4

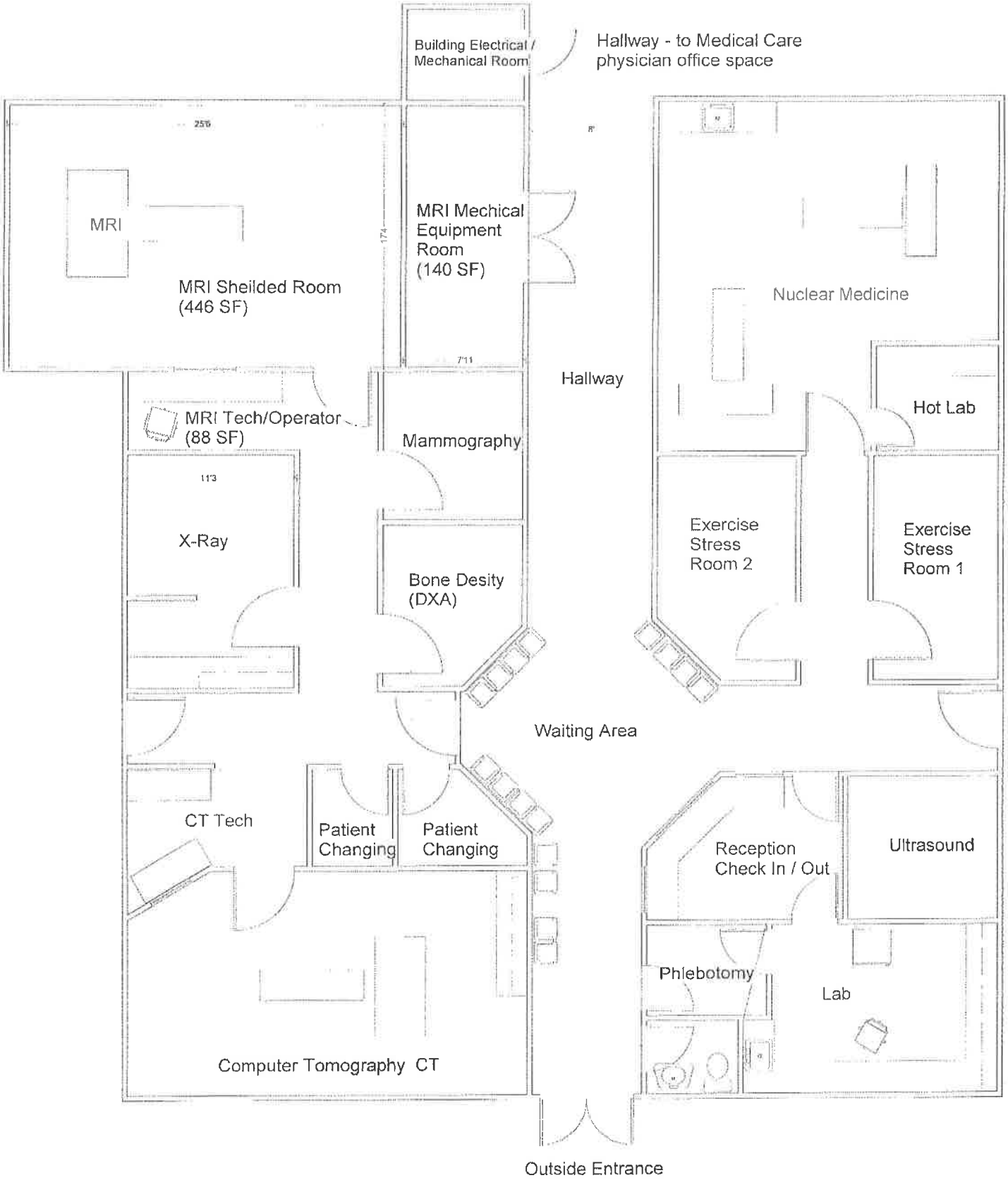
ATTACHMENT B.IV.



Medical Care, PLLC - MRI Suite

Total 674 SF

Medical Care, PLLC Radiology Suite in existing office space



ATTACHMENT

C.1.a.MRI Standards and Criteria 7.c.

ACR Guidance Document for Safe MR Practices: 2007

Emanuel Kanal[1]
A. James Barkovich[2]
Charlotte Bell[3]
James P. Borgstede[4]
William G. Bradley, Jr.[5]
Jerry W. Froelich[6]
Tobias Gilk[7]
J. Rod Gimbel[8]
John Gosbee[9]
Ellisa Kuhni-Kaminski[1]
James W. Lester, Jr.[10]
John Nyenhuis[11]
Yoav Parag[1]
Daniel J. Schaefer[12]
Elizabeth A. Sebek-Scoumis[1]
Jeffrey Weinreb[13]
Loren A. Zaremba[14]
Pamela Wilcox[15]
Leonard Lucey[15]
Nancy Sass[15]
for the ACR Blue Ribbon Panel on MR Safety

Keywords: MR contrast agents, MRI, safety

DOI:10.2214/AJR.06.1616

Received December 8, 2006; accepted without revision December 18, 2006.

E. Kanal is a consultant for, is a member of the speakers bureau of, and provides research support for Bracco Diagnostics and GE Healthcare; is a member of the speakers bureau of and provides research support for Siemens Medical Solutions; and provides research support for Berlex and Medtronic.
T. Gilk is a consultant for Mednovus, Inc.
J. R. Gimbel provides research support for St. Jude Medical, Medtronic, and Biotronik.
J. Nyenhuis is a consultant for and provides research support to Medtronics.
J. Weinreb is a consultant and member of the speakers bureau for GE Healthcare.

AJR 2007; 188:1–27

0361–803X/07/1886–1

There are potential risks in the MR environment, not only for the patient [1, 2] but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. [3–6]. There have been reports in the medical literature and print media detailing magnetic resonance imaging (MRI) adverse incidents involving patients, equipment, and personnel that spotlighted the need for a safety review by an expert panel. To this end, the American College of Radiology (ACR) originally formed the Blue Ribbon Panel on MR Safety. First constituted in 2001, the panel was charged with reviewing existing MR safe practices and guidelines [5–9] and issuing new ones as appropriate for MR examinations. Published initially in 2002 [3], the ACR MR Safe Practice Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. These were subsequently reviewed and updated in May 2004 [4]. After reviewing substantial feedback from the field and installed bases, as well as changes that had transpired throughout the MR industry since the publication of the 2004 version of this document, the panel extensively reviewed, modified, and updated the entire document in 2006–2007.

The present panel consists of the following members: A. James Barkovich, MD; Charlotte Bell, MD (American Society of Anesthesiologists); James P. Borgstede, MD, FACR; William G. Bradley, MD, PhD, FACR; Jerry W. Froelich, MD; Tobias Gilk, architect; J. Rod Gimbel, MD, FACC, cardiologist; John Gosbee, MD, MS; Ellisa Kuhni-Kaminski, RT (R)(MR); Emanuel Kanal, MD, FACR, FISMRM (chair); James W. Lester, MD; John Nyenhuis, PhD; Yoav Parag, MD; Daniel Joe Schaefer, PhD, engineer; Elizabeth A. Sebek-Scoumis, RN, BSN, CRN; Jeffrey Weinreb, MD; Loren A. Zaremba, PhD, FDA; Pamela Wilcox, RN, MBA (ACR staff); Leonard Lucey, JD, LLM (ACR staff); and Nancy Sass, RT (R)(MR)(CT) (ACR staff). The following represents the most recently modified and updated version of the combined prior two re-

[1]Department of Radiology, University of Pittsburgh Medical Center, Pittsburgh, PA.
[2]Neuroradiology Section, University of California San Francisco, San Francisco, CA.
[3]American Society of Anesthesiologists and Department of Anesthesiology, New York University School of Medicine, New York, NY.
[4]Colorado Springs Radiologists, Colorado Springs, CO.
[5]Professor and Chairman, Department of Radiology, University of California San Diego, San Diego, CA.
[6]Department of Radiology, University of Minnesota, Minneapolis, MN.
[7]MRI-Planning, Kansas City, MO.
[8]East Tennessee Heart Consultants, Lenoir City, TN.
[9]University of Michigan Health System and Red Forest Consulting, Ann Arbor, MI.
[10]Chapel Hill, NC.
[11]Department of Electrical and Computer Engineering, Purdue University, West Lafayette, IN.
[12]MR Systems Engineering, GE Healthcare, Milwaukee, WI.
[13]Yale University School of Medicine, New Haven, CT.
[14]U.S. Food and Drug Administration, Rockville, MD.
[15]American College of Radiology, 1891 Preston White Dr., Reston, VA 20191. Address correspondence to N. Sass.

ports [3, 4] issued by the American College of Radiology Blue Ribbon Panel on MR Safety, chaired by Emanuel Kanal, MD, FACR. It is important to note that nothing that appears herein is the result of a "majority vote" of the members of this panel. As with each prior publication of these ACR MR Safe Practice Guidelines, the entire document, from introduction to the markedly expanded appendices, represents the unanimous consensus of each and every member of this Safety Committee and the various areas of expertise that they represent. This includes representation from fields and backgrounds as diverse as MR physicists, research/academic radiologists, private practice radiologists, MR safety experts, patient safety experts/researchers, MR technologists, MR nursing, National Electrical Manufacturers Association, the U.S. Food and Drug Administration (FDA), the American Society of Anesthesiologists, legal counsel, and others. Lay personnel, physicians, PhDs, department chairs and house-staff/residents, government employees and private practitioners, doctors, nurses, technologists, radiologists, anesthesiologists, cardiologists, attorneys—these are all represented on this Committee. It was felt that achieving unanimity for these guidelines was critical in order to demonstrate to all that these guidelines are not only appropriate from a scientific point of view, but are reasonably applicable in the real world in which we all must live, with all its patient care, financial, and throughput pressures and considerations.

The following MR safe practice guidelines document is intended to be used as a template for MR facilities to follow in the development of an MR safety program. These guidelines were developed to help guide MR practitioners regarding these issues and to provide a basis for them to develop and implement their own MR policies and practices. It is intended that these MR safe practice guidelines (and the policies and procedures to which they give rise) be reviewed and updated on a regular basis as the field of MR safety continues to evolve.

The principles behind these MR safe practice guidelines are specifically intended to apply not only to diagnostic settings but also to patient, research subject, and health care personnel safety for all MRI settings, including those designed for clinical diagnostic imaging, research, interventional, and intraoperative MR applications.

With the increasing advent and use of 3.0-Tesla and higher strength magnets, users need to recognize that one should never assume MR compatibility or safety information about a device if it is not clearly documented in writing. Decisions based on published MR safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields.

Finally, there are many issues that impact MR safety that should be considered during site planning for a given MR installation. These have historically not been dealt with in the prior versions of the ACR MR Safe Practice Guidelines. For the first time, we include in this article, as separate appendices, sections that address such issues as well, including cryogen emergency vent locations and pathways, 5-gauss lines, siting considerations, patient access pathways, etc. Yet despite their appearance herein, these issues, and many others, should be reviewed with those experienced in MR site planning and familiar with the patient safety and patient flow considerations prior to committing to construction of a specific site design. In this regard, enlisting the assistance of an architectural firm experienced in this area, and doing so early in the design stages of the planning process, may prove most valuable.

It remains the intent of the ACR that these MR Safe Practice Guidelines will prove helpful as the field of MRI continues to evolve and mature, providing MR services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.

ACR Guidance Document for Safe MR Practices: 2007

A. Establish, Implement, and Maintain Current MR Safety Policies and Procedures

1. All clinical and research MR sites, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or surgical applications, should maintain MR safety policies.
2. These policies and procedures should also be reviewed concurrently with the introduction of any significant changes in safety parameters of the MR environment of the site (e.g., adding faster or stronger gradient capabilities or higher RF duty cycle studies) and updated as needed. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing local guidelines, policies, and procedures.
3. Each site will name an MR medical director whose responsibilities will include ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site. It is the responsibility of the site's administration to ensure that the policies and procedures that result from these MR safe practice guidelines are implemented and adhered to at all times by all of the site's personnel.
4. Procedures should be in place to ensure that any and all adverse events, MR safety incidents, or "near incidents" that occur in the MR site are reported to the medical director in a timely fashion (e.g., within 24 hours or 1 business day of their occurrence) and used in continuous quality improvement efforts. It should be stressed that the Food and Drug Administration states that it is incumbent upon the sites to also report adverse events and incidents to them via their MedWatch program. The ACR supports this requirement and feels that it is in the ultimate best interest of all MR practitioners to create and maintain this consolidated database of such events to help us all learn about them and how to better avoid them in the future [10, 11].

B. Static Magnetic Field Issues: Site Access Restriction

1. Zoning

The MR site is conceptually divided into four Zones (see Figure 1 and Appendix 1):

a. Zone I: This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

b. Zone II: This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MR personnel (see section B.2.b, below). It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.

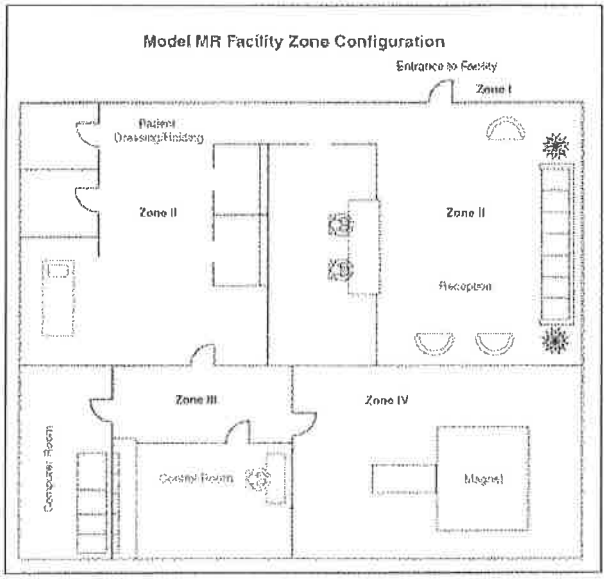


Fig. 1—Idealized sample floor plan illustrates site access restriction considerations. Other MR potential safety issues, such as magnet site planning related to fringe magnetic field considerations, are not meant to be include herein. See Appendix 1 for personnel and zone definitions. Note—In any zone of the facility, there should be compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations in regard to privacy of patient information. However, in Zone III, there should be a privacy barrier so that unauthorized persons cannot view control panels.

c. Zone III: This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel (see section B.2.b, below). Specifically identified MR personnel (typically, but not necessarily only, the MR technologists) are to be charged with ensuring that this MR safe practice guideline is strictly adhered to for the safety of the patients and other non-MR personnel, the health care personnel, and the equipment itself. This function of the MR personnel is directly under the authority and responsibility of the MR medical director or the level 2 MR personnel–designated (see section B.2.b, below) physician of the day for the MR site.

Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method that can differentiate between MR personnel and non-MR personnel. The use of combination locks is discouraged as combinations often become more widely distributed than initially intended, resulting in site restriction violations being more likely with these devices. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III.

There should be *no* exceptions to this guideline. Specifically, this includes hospital or site administration, physician, security, and other non-MR personnel (see section B.2.c, below). Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at the very least the area within it wherein the static magnetic field's strength exceeds 5 gauss, should be demarcated and clearly marked as being potentially hazardous.

Because magnetic fields are three-dimensional volumes, Zone III controlled access areas may project through floors and ceilings of MRI suites, imposing magnetic field hazards on persons on floors other than that of the MR scanner. Zones of magnetic field hazard should be clearly delineated, even in typically nonoccupied areas such as rooftops or storage rooms, and access to these Zone III areas should be similarly restricted from non-MR personnel as they would be inside any other Zone III region associated with the MRI suite. For this reason, magnetic field strength plots for all MRI systems should be analyzed in vertical section as well as in horizontal plan, identifying areas above or below, in addition to areas on the same level, where persons may be at risk of interactions with the magnetic field.

d. Zone IV: This area is synonymous with the MR scanner magnet room itself, that is, the physical confines of the room within which the MR scanner is located. Zone IV, by definition, will always be located within Zone III, as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. As part of the Zone IV site restriction, all MR installations should provide for direct visual observation by level 2 personnel to access pathways into Zone IV. By means of illustration only, the MR technologists would be able to directly observe and control, via line of sight or via video monitors, the entrances or access corridors to Zone IV from their normal positions when stationed at their desks in the scan control room.

Zone IV should be clearly marked with a red light and lighted sign stating, "The Magnet is On." Except for resistive systems, this light and sign should be illuminated at all times and should be provided with a backup energy source to continue to remain illuminated for at least 24 hours in the event of a loss of power to the site.

In case of cardiac or respiratory arrest or other medical emergency within Zone IV for which emergent medical intervention or resuscitation is required, appropriately trained and certified MR personnel should immediately initiate basic life support or CPR as required by the situation *while* the patient is being emergently removed from Zone IV to a predetermined, magnetically safe location. *All* priorities should be focused on stabilizing (e.g., basic life support with cardiac compressions and manual ventilation) and then evacuating the patient as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts.

Further, for logistical safety reasons, the patient should always be moved from Zone IV to the prospectively identified location where full resuscitative efforts are to continue. (See Appendix 2.)

Quenching the magnet (for superconducting systems only) is not routinely advised for cardiac or respiratory arrest or other medical emergency, since quenching the magnet and having the magnetic field dissipate could easily take more than a minute. Further-

more, as quenching a magnet can theoretically be hazardous, ideally one should evacuate the magnet room, when possible, for an intentional quench. One should rather use that time wisely to initiate life support measures while removing the patient from Zone IV to a location where the strength of the magnetic field is insufficient to be a medical concern. Zones III and IV site access restriction *must* be maintained during resuscitation and other emergent situations for the protection of all involved.

2. MR personnel and non-MR personnel

a. All individuals working within at least Zone III of the MR environment should be documented as having successfully completed at least one of the MR safety live lectures or prerecorded presentations approved by the MR medical director. Attendance should be repeated at least annually, and appropriate documentation should be provided to confirm these ongoing educational efforts. These individuals shall be referred to henceforth as MR personnel.

b. There are two levels of MR personnel:

   1. Level 1 MR personnel: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to henceforth as level 1 MR personnel.
   2. Level 2 MR personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to henceforth as level 2 MR personnel. It is the responsibility of the MR medical director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MR personnel. It is understood that the medical director will have the necessary education and experience in MR safety to qualify as level 2 MR personnel. (See Appendix 1.)

c. All those not having successfully complied with this MR safety instruction guideline shall be referred to henceforth as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

3. Patient and non-MR personnel screening

a. *All* non-MR personnel wishing to enter Zone III must first pass an MR safety screening process. Only MR personnel are authorized to perform an MR safety screen before permitting non-MR personnel into Zone III.

b. The screening process and screening forms for patients, non-MR personnel, and MR personnel should be essentially identical. Specifically, one should assume that non-MR personnel, health care practitioners, or MR personnel may enter the bore of the MR imager during the MR imaging process.

   Examples of this might include when a pediatric patient cries for his mother, who then leans into the bore, or when the anesthetist leans into the bore to manually ventilate a patient in the event of a problem.

c. Metal detectors

   The usage in MR environments of conventional metal detectors which do not differentiate between ferrous and nonferromagnetic materials is not recommended. Reasons for this recommendation against conventional metal detector usage include, among others:

   1. They have varied—and variable—sensitivity settings.
   2. The skills of the operators can vary.
   3. Today's conventional metal detectors cannot detect, for example, a 2 × 3 mm, potentially dangerous ferromagnetic metal fragment in the orbit or near the spinal cord or heart.
   4. Today's conventional metal detectors do not differentiate between ferromagnetic and nonferromagnetic metallic objects, implants, or foreign bodies.
   5. Metal detectors should not be necessary for the detection of large metallic objects, such as oxygen tanks on the gurney with the patients. These objects are fully expected to be detected—and physically excluded—during the routine patient screening process.

      However, ferromagnetic detection systems are currently available that are simple to operate, capable of detecting even very small ferromagnetic objects external to the patient, and now, for the first time, differentiating between ferromagnetic and nonferromagnetic materials. While the use of conventional metal detectors is not recommended, the use of **ferromagnetic detection systems** is recommended as an adjunct to thorough and conscientious screening of persons and devices approaching Zone IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage.

d. Non-MR personnel should be accompanied by, or under the immediate supervision of and in visual or verbal contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions. However, it is acceptable to have non-MR personnel in a changing room or restroom in Zone III without visual contact as long as the personnel and the patient can communicate verbally with each other.

   Level 1 MR personnel are permitted unaccompanied access throughout Zones III and IV. Level 1 MR personnel are also explicitly permitted to be responsible for accompanying non-MR personnel into and throughout Zone III, excluding Zone IV. However, level 1 MR personnel are *not* permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

   In the event of a shift change, lunch break, etc., no level 2 MR personnel shall relinquish their responsibility to supervise non-MR personnel still within Zone III or Zone IV until such supervision has been formally transferred to another of the site's level 2 MR personnel.

e. Nonemergent patients should be MR safety–screened on site by a minimum of 2 separate individuals. At least one of these individuals should be level 2 MR personnel. At least one of these 2 screenings should be performed verbally or interactively.

   Emergent patients and their accompanying non-MR personnel may be screened only once, providing the screening individual is level 2 MR personnel. There should be no exceptions to this.

f. Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches, jewelry, pagers, cell phones, body piercings [if removable], contraceptive diaphragms, metallic

drug delivery patches [see section I, below], cosmetics containing metallic particles [such as eye make-up], and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads). It is therefore advisable to require that the patients or research subjects wear a site-supplied gown with no metal fasteners when feasible.

g. All patients and non-MR personnel with a history of potential ferromagnetic foreign object penetration must undergo further investigation prior to being permitted entrance to Zone III. Examples of acceptable methods of screening include patient history, plain X-ray films, prior CT or MR studies of the questioned anatomic area, or access to written documentation as to the type of implant or foreign object that might be present. Once positive identification has been made as to the type of implant or foreign object that is within a patient, best-effort assessments should be made to identify the MR compatibility or MR safety of the implant or object. Efforts at identification might include written records of the results of formal testing of the implant prior to implantation (preferred), product labeling regarding the implant or object, and review of peer-reviewed publications regarding MR compatibility and MR safety testing of the make, model, and type of the object. MR safety testing would be of value only if the object or device had not been altered since such testing results had been published.

   All patients who have a history of orbit trauma by a potential ferromagnetic foreign body *for which they sought medical attention* are to have their orbits cleared either by plain X-ray orbit films (2 views) [12, 13] or by a radiologist's review and assessment of contiguous cut prior CT or MR images (obtained since the suspected traumatic event), if available.

h. Conscious, nonemergent patients and research and volunteer subjects are to complete written MR safety screening questionnaires prior to their introduction to Zone III. Family or guardians of nonresponsive patients or of patients who cannot reliably provide their own medical histories are to complete a written MR safety screening questionnaire prior to their introduction to Zone III. These completed questionnaires are then to be reviewed orally with the patient, guardian, or research subject in their entirety prior to permitting the patient or research subject to be cleared into Zone III.

   The patient, guardian, or research subject as well as the screening MR staff member must both sign the completed form. This form should then become part of the patient's medical record. No empty responses will be accepted—each question *must* be answered with a "yes" or "no" or specific further information must be provided as requested. A sample pre-MR screening form is provided (see Appendix 3). This is the minimum information to be obtained; more may be added if the site so desires.

i. Screening of the patient or non-MR personnel with, or suspected of having, an intracranial aneurysm clip should be performed as per the separate MR safe practice guideline addressing this particular topic (see section M, below).

j. Screening of patients for whom an MR examination is deemed clinically indicated or necessary, but who are unconscious or unresponsive, who cannot provide their own reliable histories regarding prior possible exposures to surgery, trauma, or metallic foreign objects, and for whom such histories cannot be reliably obtained from others:

   1. If no reliable patient metal exposure history can be obtained, and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that such patients be physically examined by level 2 MR personnel. All areas of scars or deformities that might be anatomically indicative of an implant, such as on the chest or spine region, and whose origins are unknown and which may have been caused by ferromagnetic foreign bodies, implants, etc., should be subject to plain-film radiography (if recently obtained plain films or CT or MR studies of such areas are not already available). The investigation described above should be made to ensure there are no potentially harmful embedded or implanted metallic foreign objects or devices. All such patients should also undergo plain film imaging of the skull or orbits and chest to exclude metallic foreign objects (if recently obtained plain films or CT or MR studies of such areas are not already available).
   2. Monitoring of patients in the MR scanner is sometimes necessary. The potential for thermal injury from excessive RF[2] power deposition exists. Sedated, anesthetized, or unconscious patients may not be able to express symptoms of such injury. This potential for injury is greater on especially higher-field whole-body scanners (e.g., 1 Tesla and above). Distortion of the electrocardiogram within the magnetic field makes interpretation of the ECG complex unreliable, even with filtering used by contemporary monitoring systems. However, routine monitoring of heart rate and rhythm may be accomplished using pulse oximetry, which also eliminates the risks of thermal injury from electrocardiography. Patients who require ECG monitoring and who are unconscious, sedated, or anesthetized should be examined after each imaging sequence, with potential repositioning of the ECG leads and any other electrically conductive material with which the patient is in contact. Alternatively, cold compresses or ice packs could be placed upon all necessary electrically conductive material that touches the patient during scanning.

k. Final determination of whether or not to scan any given patient with any given implant, foreign body, etc., is to be made by the level 2 MR personnel–designated attending MR radiologist, the MR medical director, or specifically designated level 2 MR personnel following criteria for acceptability predetermined by the medical director.

   For implants that are strongly ferromagnetic, an obvious concern is that of magnetic translational and rotational forces upon the implant which might move or dislodge the device from its implanted position. If an implant has demonstrated weak ferromagnetic forces on formal testing, it might be prudent to wait several weeks for fibrous scarring to set in, as this may help anchor the implant in position and help it resist such weakly attractive magnetic forces that might arise in MR environments.

   For all implants that have been demonstrated to be nonferrous in nature, however, the risk of implant motion is essentially reduced to those resulting from Lenz's forces alone. These tend to be quite trivial for typical metallic implant sizes of a few centimeters or less. Thus, a waiting period for fibrous scarring to set in is far less important, and the advisability for such a waiting period may well be easily outweighed by the potential clinical benefits of undergoing an MR examination at that time. As always, clinical assessment of the risk–benefit ratio for the par-

ticular clinical situation and patient at hand are paramount for appropriate medical decision making in these scenarios.

It is possible that during the course of an MRI examination an unanticipated ferromagnetic implant or foreign body is discovered within a patient or research subject undergoing the examination. This is typically suspected or detected by means of a sizable field-distorting artifact seen on spin-echo imaging techniques that grows more obvious on longer TE studies and expands markedly on typical moderate or long TE gradient-echo imaging sequences. In such cases, it is imperative that the medical director, safety officer, and/or physician in charge be immediately notified of the suspected findings. This individual should then assess the situation, review the imaging information obtained, and decide what the best course of action might be.

It should be noted that there are numerous potentially acceptable courses that might be recommended which in turn depend upon many factors, including the status of the patient, the location of the suspected ferromagnetic implant/foreign body relative to local anatomic structures, the mass of the implant, etc. Appropriate courses of action might include proceeding with the scan under way, immobilizing the patient and the immediate removal of the patient from the scanner, or other intermediate steps. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the patient from the scanner bore. Further, the greater the rate of motion of the patient/device through the magnetic fields of the scanner bore, the greater the forces acting upon that device will likely be. Thus, it is prudent to ensure that, if at all possible, immobilization of the device during patient extraction from the bore, and the slow, cautious, deliberate rate of extricating the patient from the bore, will likely result in weaker and potentially less harmful forces on the device as it traverses the various static magnetic field gradients associated with the MR imager.

It is also worthy of note that the magnetic fields associated with the MR scanner are distributed throughout space three-dimensionally. Thus, especially for superconducting systems, one should avoid the temptation to have the patient sit up as soon as he or she is physically out of the bore. Doing so may expose the ferrous object to still-significant torque- and translation-related forces despite the patient's being physically outside the scanner bore. It is therefore advisable to continue to extract the patient along a straight line course parallel to the center of the magnet while the patient remains immobilized until they are as far as physically possible from the MR imager itself, before any other patient/object motion vector is attempted or permitted.

l. All non-MR personnel (e.g., patients, volunteers, varied site employees, and professionals) with implanted cardiac pacemakers, autodefibrillators, diaphragmatic pacemakers, or other electromechanically activated devices upon which the non-MR personnel is dependent should be precluded from Zone IV and physically restrained from the 5-gauss line unless specifically cleared in writing by a level 2 MR personnel–designated attending radiologist or the medical director of the MR site. In such circumstances, a specific defending risk–benefit rationale should be provided in writing and signed by the authorizing radiologist.

Should it be determined that non-MR personnel wishing to accompany a patient into an MR scan room require their orbits to be cleared by plain-film radiography, a radiologist must first discuss with the non-MR personnel that plain X-ray films of their orbits are required prior to permitting them access to the MR scan room. Should they still wish to proceed with access to Zone IV or within the 5-gauss line, and should the attending radiologist deem it medically advisable that they do so (e.g., for the care of their child about to undergo an MR study), written informed consent should be provided by these accompanying non-MR personnel prior to their undergoing X-ray examination of their orbits.

m. MR scanning of patients, prisoners, or parolees with metallic prisoner-restraining devices or RF ID or tracking bracelets could lead to theoretic adverse events, including: (1) ferromagnetic attractive effects and resultant patient injury, (2) possible ferromagnetic attractive effects and potential damage to the device or its battery pack, (3) RF interference with the MRI study and secondary image artifact, (4) RF interference with the functionality of the device, (5) RF power deposition and heating of the bracelet or tagging device or its circuitry and secondary patient injury (if the bracelet were in the anatomic volume of the RF transmitter coil being used for imaging). Therefore, when requested to scan a patient, prisoner, or parolee wearing RF bracelets or metallic handcuffs or ankle cuffs, request that the patient be accompanied by the appropriate authorities who can and will remove the restraining device prior to the MR study and be charged with its replacement following the examination.

n. Firefighter, police, and security safety considerations: For the safety of firefighters and other emergent services responding to an emergent call at the MR site, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR site should be forwarded simultaneously to a specifically designated individual from among the site's MR personnel. This individual should, if possible, be on site prior to the arrival of the firefighters or emergent responders to ensure that they do not have free access to Zone III or Zone IV. The site might consider assigning appropriately trained security personnel, who have been trained and designated as MR personnel, to respond to such calls.

In any case, all MR sites should arrange to prospectively educate their local fire marshals, firefighters' associations, and police or security personnel about the potential hazards of responding to emergencies in the MR suite.

It should be stressed that even in the presence of a true fire (or other emergency) in Zone III or Zone IV, the magnetic fields may be present and fully operational. Therefore, free access to Zone III or Zone IV by firefighters or other non-MR personnel with air tanks, axes, crowbars, other firefighting equipment, guns, etc., might prove catastrophic or even lethal to those responding or to others in the vicinity.

As part of the Zone III and Zone IV restrictions, all MR sites must have clearly marked, readily accessible MR-conditional or MR-safe fire extinguishing equipment physically stored in Zone III or Zone IV. All conventional fire extinguishers and other firefighting equipment not tested and verified safe in the MR environment should be restricted from Zone III.

For superconducting magnets, the helium (and the nitrogen as well, in older MR magnets) is not flammable and does not pose a fire hazard directly. However, the liquid oxygen that can result from the supercooled air in the vicinity of the released

gases might well increase the fire hazard in this area. If there are appropriately trained and knowledgeable MR personnel available during an emergency to ensure that emergency response personnel are kept out of the MR scanner or magnet room and away from the 5-gauss line, quenching the magnet during a response to an emergency or fire should not be a requirement.

However, if the fire is in such a location where Zone III or Zone IV needs to be entered for whatever reason by firefighting or emergency response personnel and their firefighting and emergent equipment, such as air tanks, crowbars, axes, and defibrillators, a decision to quench a superconducting magnet should be *very* seriously considered to protect the health and lives of the emergent responding personnel. Should a quench be performed, appropriately designated MR personnel still need to ensure that *all* non-MR personnel (including and especially emergent response personnel) continue to be restricted from Zones III and IV until the designated MR personnel has personally verified that the static field is either no longer detectable or at least sufficiently attenuated as to no longer present a potential hazard to one moving by it with, for example, large ferromagnetic objects such as air tanks or axes.

For resistive systems, the magnetic field of the MR scanner should be shut down as completely as possible and verified as such prior to permitting the emergency response personnel access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR personnel should ideally be available to warn the emergency response personnel that a very powerful magnetic field is still operational in the magnet room.

4. MR personnel screening

All MR personnel are to undergo an MR screening process as part of their employment interview process to ensure their safety in the MR environment. For their own protection and for the protection of the non-MR personnel under their supervision, all MR personnel must immediately report to the MR medical director any trauma, procedure, or surgery they experience or undergo in which a ferromagnetic metallic object or device may have become introduced within or on them. This will permit appropriate screening to be performed on the employee to determine the safety of permitting that employee into Zone III.

5. Device and object screening

Ferrous objects, including those brought by patients, visitors, contractors, etc., should be restricted from entering Zone III, whenever practical.

As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (≥ 1000 gauss). This will enable the site to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

a. All portable metallic or partially metallic devices that are on or external to the patient (e.g., oxygen cylinders) are to be positively identified in writing as ferromagnetic or, alternatively, nonferromagnetic and safe or conditionally safe in the MR environment prior to permitting them into Zone III. For all device or object screening, verification and positive identification should be in writing. Examples of devices that need to be positively identified include fire extinguishers, oxygen tanks, and aneurysm clips.
b. External devices or objects demonstrated to be ferromagnetic and MR unsafe or incompatible in the MR environment may still, under specific circumstances, be brought into Zone III if, for example, they are deemed by MR personnel to be necessary and appropriate for patient care. They should only be brought into Zone III if they are under the direct supervision of specifically designated level 1 or level 2 MR personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone III. The safe utilization of these devices while they are present in Zone III will be the responsibility of specifically named level 1 or 2 MR personnel. These devices must be appropriately physically secured or restricted at all times during which they are in Zone III to ensure that they do not inadvertently come too close to the MR scanner and accidentally become exposed to static magnetic fields or gradients that might result in their becoming either hazardous projectiles or no longer accurately functional.
c. Never assume MR compatibility or safety information about the device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction beyond Zone II should be tested with a strong handheld magnet (≥ 1000 gauss) for ferromagnetic properties before permitting them entry to Zone III. The results of such testing, as well as the date, time, and name of the tester, and methodology used for that particular device, should be documented in writing. If a device has not been tested, or if its MR compatibility or safety status is unknown, it should *not* be permitted unrestricted access to Zone III.
d. All portable metallic or partially metallic objects that are to be brought into Zone IV must be properly identified and appropriately labeled utilizing the current FDA labeling criteria developed by ASTM (American Society for Testing and Materials) International (http://www.astm.org) (see Fig. 2). Those items which are wholly nonmetallic should be identified with a square green "MR safe" label. Items which are clearly ferromagnetic should be identified as "not MR safe" and labeled appropriately with the corresponding round red label with a slash through it. Objects with an "MR conditional" rating should be affixed with a triangular yellow MR conditional label prior to being taken into the scan room/Zone IV.

As noted in the introduction to this section B.5, above, if MR safety data are not prospectively available for a given device, initial testing for the purpose of this labeling is to be accomplished by the site's MR personnel by exposing the metallic object to a handheld magnet (≥ 1000 gauss). If grossly detectable attractive forces are observed between the object being tested or any of its components and the handheld magnet, it is to be labeled with a circular red "not MR safe" label. If no or negligible attractive forces are observed, a triangular yellow "MR conditional" label is to be attached to the object. It is only when the composition of an object and its components are known to be nonmetallic that the green "MR safe" label is to be affixed to a device or object.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as "non-magnetic," or outdated classifications such as "MR-compatible," should not be presumed to conform to a particular current ASTM classification. Similarly, any product marketed as "MR safe" but with metallic construction or components should be treated with suspicion. Objects intended for

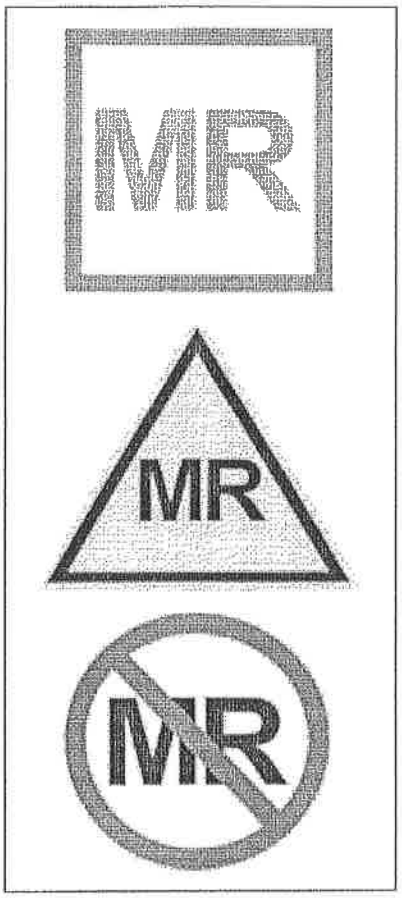


Fig. 2—U.S. Food and Drug Administration labeling criteria (developed by ASTM [American Society for Testing and Materials] International) for portable objects taken into Zone IV. Square green "MR safe" label is for wholly nonmetallic objects, triangular yellow label is for objects with "MR conditional" rating, and round red label is for "not MR safe" objects.

use in Zone IV, including nonclinical incidental products such as stepping stools or ladders, which are not provided with manufacturer or third-party MR safety test results under the new ASTM criteria, should be site tested as described above.

e. Decisions based on published MR compatibility or safety claims should recognize that all such claims apply to specifically tested static field and static gradient field strengths—for example, "MR conditional, having been tested to be safe up to 3.0 Tesla at gradient strengths of 400 G/cm," or "MR conditional, having been tested to be safe up to 1.5 Tesla up to maximum static gradient fields experienced in an unshielded 1.5-Tesla [manufacturer's name] whole-body MR scanner tested 1.5 feet within the bore."

f. It should be noted that alterations performed by the site on MR safe, MR unsafe, and MR conditional equipment or devices may alter the MR safety or compatibility properties of the device. For example, tying a ferromagnetic metallic twisting binder onto a sign labeling the device as MR conditional or MR safe might result in artifact induction—or worse—if introduced into the MR scanner.

Lenz's Forces:

Faraday's law states that a moving or changing magnetic field will induce a voltage in a perpendicularly oriented electrical conductor. Lenz's law builds upon this and states that the induced voltage will itself be such that it will secondarily generate its own magnetic field whose orientation and magnitude will oppose those of the initial time-varying magnetic field that created it in the first place. For example, if an electrical conductor is moved perpendicularly toward the magnetic field, B_0, of an MR scanner, even if this conductor is not grossly ferromagnetic, the motion itself will result in the generation of voltages in this conductor whose magnitude is directly proportional to the rate of motion as well as the spatial gradient of the magnetic field, B_0, through which it is being moved. Conducting objects turning in the static field will also experience a torque due to the induced eddy currents. Lenz's law states that this induced current will in turn create a magnetic field whose orientation will oppose the B_0 magnetic field that created this current.

Thus, moving a large metallic but nonferromagnetic electrical conductor toward the magnet bore will result in the induction of a voltage and associated magnetic field which will orient in such a manner and at such a strength as to oppose the motion of the metallic object into the bore of the MR scanner. If, for example, one tries to move a nonferrous oxygen tank into the bore of an MR scanner, as the scanner bore is approached Lenz's forces will be sufficiently strong to virtually stop forward progress of the tank. Further, the faster one moves the tank into the bore, the greater the opposing force that is created to stop this motion.

This also has potential consequences for large implanted metallic devices such as certain metallic nonferrous infusion pumps. Although they may not pose a projectile hazard, rapid motion of the patient/implant perpendicular to the magnetic field of the MR imager can be expected to result in forces on the implant that would oppose this motion and may likely be detected by the patient. If the patient were to complain of experiencing forces tugging or pulling on the implant, this might bring the patient or health care personnel to erroneously conclude that there were ferrous components to the device, which might lead to cancellation of the examination. Slowly moving such large metallic devices into and out of the bore is a key factor in decreasing any Lenz's forces that might be induced and in decreasing the likelihood of a misunderstanding or an unnecessary study cancellation.

C. MR Technologists

1. MR technologists should be ARRT (American Registry of Radiologic Technologists)–registered technologists (RTs). Furthermore, all MR technologists must be trained as level 2 MR personnel during their orientation prior to being permitted free access to Zone III.
2. All MR technologists will maintain current certification in American Heart Association basic life support at the health care provider level.
3. Except for emergent coverage, there will be a minimum of 2 MR technologists or one MR technologist and one other individual with the designation of MR personnel in the immediate Zone II through Zone IV MR environment. For emergent coverage, the MR technologist can scan with no other individuals in their Zone II through Zone IV environment as long as there is in-house, ready emergent coverage by designated department of radiology MR personnel (e.g., radiology house staff or attending radiologist).

D. Pregnancy-Related Issues

1. Health care practitioner pregnancies

Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy [14]. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast material, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning.

2. Patient pregnancies

Present data have not conclusively documented any deleterious effects of MR imaging exposure on the developing fetus. Therefore, no special consideration is recommended for the first, versus any other, trimester in pregnancy. Nevertheless, as with all interventions during pregnancy, it is prudent to screen women of reproductive age for pregnancy prior to permitting them access to MR imaging environments. If pregnancy is established, consideration should be given to reassessing the potential risks versus benefits of the pending study in determining whether performance of the requested MR examination could safely wait until the end of the pregnancy.

a. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel–designated attending radiologist, the risk–benefit ratio to the patient warrants that the study be performed. The radiologist should confer with the referring physician and document the following in the radiology report or the patient's medical record:
   1. The information requested from the MR study cannot be acquired via nonionizing means (e.g., ultrasonography).
   2. The data are needed to potentially affect the care of the patient or fetus *during* the pregnancy.
   3. The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.
b. MR contrast agents should *not* be routinely provided to pregnant patients. This decision, too, is one that must be made on a case-by-case basis by the covering level 2 MR personnel–designated attending radiologist who will assess the risk–benefit ratio for that particular patient.

   The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk–benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus outweighing the theoretic but potentially real risks of long-term exposure of the developing fetus to free gadolinium ions.

   Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation. From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location the gadolinium-chelate molecules are in a relatively protected space and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects.

   The risk to the fetus with administration of gadolinium-based MR contrast agents remains unknown and may be harmful.
c. It is recommended that pregnant patients undergoing an MR examination provide written informed consent documenting that they understand the potential risks and benefits of the MR procedure to be performed, are aware of the alternative diagnostic options available to them (if any), and wish to proceed.

E. Pediatric MR Safety Concerns

1. Sedation and monitoring issues

Children form the largest group requiring sedation for MRI, largely because of their inability to remain motionless during scans. Sedation protocols may vary from institution to institution according to the procedures performed (diagnostic vs interventional), the complexity of the patient population (healthy preschoolers vs premature infants), the method of sedation (mild sedation vs general anesthesia), and the qualifications of the sedation provider.

Adherence to standards of care mandates following the sedation guidelines developed by the American Academy of Pediatrics [15, 16], the American Society of Anesthesiologists [17], and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [18]. In addition, sedation providers must comply with protocols established by the individual state and the practicing institution. These guidelines require the following provisions:

a. Preprocedural medical history and examination for each patient
b. Fasting guidelines appropriate for age
c. Uniform training and credentialing for sedation providers
d. Intraprocedural and postprocedural monitors with adaptors appropriately sized for children (compatible with the magnetic field)
e. Method of patient observation (window, camera)
f. Resuscitation equipment, including oxygen delivery and suction
g. Uniform system of record keeping and charting (with continuous assessment and recording of vital signs)
h. Location and protocol for recovery and discharge
i. Quality assurance program that tracks complications and morbidity.

For the neonatal and the young pediatric population, special attention is needed in monitoring body temperature for both hypo- and hyperthermia in addition to other vital signs [19]. Temperature monitoring equipment that is approved for use in the MR suite is becoming more readily available. Commercially available, MR-approved neonatal isolation transport units and other warming devices are also available for use during MR scans.

2. Pediatric screening issues

Children may not be reliable historians and, especially in cases of older children and teenagers, should be questioned both in the presence of parents or guardians and separately to maximize the possibility that all potential dangers are disclosed. Therefore, it is recommended that children be gowned before entering Zone IV to help ensure that no metallic objects, toys, etc. inadvertently find

their way into Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent real risks and should be discouraged from entering Zone IV. If unavoidable, each such item should be carefully checked with the powerful handheld magnet and perhaps again in the MR scanner prior to permitting the patient to enter Zone IV with the object in order to ensure that it does not contain any objectionable metallic components.

3. MR safety of accompanying family or personnel

Although any age patient might request that others accompany them for their MR examination, this is far more common in the pediatric population. Those accompanying or remaining with the patient should be screened using the same criteria as anyone else entering Zone IV.

In general, it would be prudent to limit accompanying adults to a single individual. Only a qualified, responsible MR physician should make screening criteria exceptions.

Hearing protection and MR safe/MR conditional seating are recommended for accompanying family members within the MR scan room.

F. Time-Varying Gradient Magnetic Field–Related Issues: Induced Voltages

Types of patients needing extra caution:

Patients with implanted or retained wires in anatomically or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered to be at higher risk, especially from faster MRI sequences, such as echo-planar imaging (which may be used in such sequences as diffusion-weighted imaging, functional imaging, perfusion-weighted imaging, MR angiographic imaging, etc.). The decision to limit the dB/dt (rate of magnetic field change) and maximum strength of the magnetic field of the gradient subsystems during imaging of such patients should be reviewed by the level 2 MR personnel–designated attending radiologist supervising the case or patient.

G. Time-Varying Gradient Magnetic Field–Related Issues: Auditory Considerations

1. All patients and volunteers should be offered and encouraged to use hearing protection prior to undergoing any imaging in the MR scanners.
2. All patients or volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been approved by the Food and Drug Administration) are to have hearing protective devices *in place* prior to the initiation of any MR sequences. Without hearing protection in place, MRI sequences that are not FDA-approved should not be performed on patients or volunteers.

H. Time-Varying Radiofrequency Magnetic Field–Related Issues: Thermal

1. All unnecessary or unused electrically conductive materials should be removed from the MR system before the onset of imaging. It is not sufficient to merely to "unplug" or disconnect unused, unnecessary electrically conductive material and leave it within the MR scanner with the patient during imaging. All electrical connections, such as on surface coil leads or monitoring devices, must be visually checked by the scanning MR technologist prior to each use to ensure the integrity of the thermal and electrical insulation.
2. Electrical voltages and currents can be induced in electrically conductive materials that are within the bore of the MR imager during the MR imaging process. This might result in the heating of this material by resistive losses. This heat might be of a caliber sufficient to cause injury to human tissue. Among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of the conductive loops, the greater the potential induced voltages or currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous patient tissue.

   Therefore, when electrically conductive material (wires, leads, implants, etc.) are required to remain within the bore of the MR scanner with the patient during imaging, care should be taken to ensure that no large-caliber electrically conducting loops (including patient tissue; see section II.5, below) are formed within the MR scanner during imaging. Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant circuitry between the transmitted RF power and the lead. This could result in very rapid and clinically significant lead heating, especially at the lead tips, in a matter of seconds to a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires, even when they are not connected to any other device at either end. For illustration, the FDA has noted several reports of serious injury, including coma and permanent neurologic impairment, in patients with implanted neurologic stimulators who underwent MR imaging examinations. The injuries in these instances resulted from heating of the electrode tips [20, 21].

   Further, it is entirely possible for a lead or wire to demonstrate no significant heating while undergoing MR imaging examinations at 1.5 Tesla, yet demonstrate clinically significant and potentially harmful degrees of heating within seconds at, for example, 3 Tesla. It has also been demonstrated that leads may show no significant heating at 3 Tesla yet may rapidly heat to hazardous levels when undergoing MR imaging at, for example, 1.5 Tesla (personal observation, MR safety testing, E. Kanal, MD, University of Pittsburgh Medical Center MR Research Center, 8/28/05). Thus, at no time should a label of "MR conditionally safe for thermal issues at [a given field strength]" be applied to any field strength, higher or lower, other than the specific one at which safety was demonstrated.

   Thus, exposure of electrically conductive leads or wires to the RF transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure significant lead or tissue heating does not result (see section II.9, below).
3. When electrically conductive materials are required to be within the bore of the MR scanner with the patient during imaging, care should be taken to place thermal insulation (including air, pads, etc.) between the patient and the electrically conductive material, while simultaneously attempting (as much as feasible) to keep the electrical conductor from directly contacting the patient during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or ice packs to such areas.
4. Depending on specific magnet designs, care may be needed to ensure that the patient's tissue(s) do not directly come into contact with the inner bore of the MR imager during the MRI process. This

is especially important for several higher-field MR scanners. The manufacturers of these devices provide pads and other such insulating devices for this purpose, and manufacturer's guidelines should be strictly adhered to for these units.

5. It is important to ensure the patient's tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patient's arms or legs are not positioned in such a way as to form a large-caliber loop within the bore of the MR imager during the imaging process. For this reason, it is preferable that patients be instructed not to cross their arms or legs in the MR scanner. We are also aware of unpublished reports of thermal injuries that seem to have been associated with skin folds, such as in the region of the inner thighs. While the cause of this is not yet fully understood, it might be prudent to consider ensuring that skin folds and other such examples of tissue-to-tissue contact are minimized or eliminated in the region undergoing radiofrequency energy irradiation.
6. Skin staples and superficial metallic sutures: Patients requested to undergo MR studies in whom there are skin staples or superficial metallic sutures (SMS) may be permitted to undergo the MR examination if the skin staples or SMS are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed. If the nonferromagnetic skin staples or SMS are within the volume to be RF-irradiated for the requested MR study, several precautions are recommended.
   a. Warn the patient and make sure that they are especially aware of the possibility that they may experience warmth or even burning along the skin staple or SMS distribution. The patient should be instructed to report immediately if they experience warmth or burning sensations during the study (and not, for example, wait until the "end of the knocking noise").
   b. It is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely clinically accomplished during the MRI examination. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.
7. For patients with extensive or dark tattoos, including tattooed eyeliner, in order to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process if these tattoos are in the volume in which the body coil is being used for RF transmission. This approach is especially appropriate if fast spin-echo (or other high RF duty cycle) MRI sequences are anticipated in the study. If another coil is being used for RF transmission, a decision must be made if high RF transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed. Additionally, patients with tattoos that had been placed within 48 hours prior to the pending MR examination should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.
8. In the unconscious or unresponsive patient, all attached leads that will be in or partly in the volume undergoing RF irradiation should be covered with a cold compress or ice pack at the lead attachment site for the duration of the MR study.
9. As noted above, it has been demonstrated that resonant circuitry can be established during MRI between the RF energies being transmitted and specific lengths of long electrically conductive wires or leads, which can thus act as efficient antennae. This can result in heating of the tips of these wires or leads to temperatures in excess of 90°C in a few seconds. Therefore, patients in whom there are long electrically conductive leads, such as Swan-Ganz thermodilution cardiac output–capable catheters or Foley catheters with electrically conductive leads, should be considered at risk for MR studies if the body coil is to be used for RF transmission over the region of the electrically conductive lead. This is especially true for higher-field systems and for imaging protocols utilizing fast spin-echo or other high-RF duty cycle MRI sequences. Each such patient should be reviewed and cleared by an attending level 2 radiologist and a risk–benefit ratio assessment performed prior to permitting them access to the MR scanner.
10. The potential to establish substantial heating is itself dependent on multiple factors, including, among others, the static magnetic field strength of the MR scanner (as this determines the transmitted radiofrequencies [RF] at which the device operates) and the length, orientation, and inductance of the electrical conductor in the RF-irradiated volume being studied. *Virtually any lead lengths can produce substantial heating.* Innumerable factors can affect the potential for tissue heating for any given lead. It is therefore critical to recognize that of all electrically conductive implants, it is specifically wires, or leads, that pose the greatest potential hazard for establishing substantial power deposition/heating considerations.

    Another important consideration is that as a direct result of the above, it has already been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at, for example, 1.5 Tesla but quite significant at 3.0 Tesla. However, it has also been demonstrated that specific implants might show no significant thermal issues or heating at 3.0 Tesla, *but may heat to clinically significant or very significant levels in seconds at, for example, 1.5 Tesla.* Thus, it is important to follow established product MR safety guidelines carefully and precisely, applying them to, and only to, the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the tested field strength(s).

I. Drug Delivery Patches and Pads

Some drug delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury [22]. Since removal or repositioning can result in altering of patient dose, consultation with the patient's prescribing physician would be indicated in assessing how to best manage the patient. If the metallic foil of the patch delivery system is positioned on the patient so that it is in the volume of excitation of the transmitting RF coil, the case should be specifically reviewed with the radiologist or physician covering the patient. Alternative options may include placing an ice pack directly on the patch. This solution may still substantially alter the rate of delivery or absorption of the medication to the patient (and be less comfortable to the patient, as well). This ramification should therefore not be treated lightly, and a decision to proceed in this manner should be made by a knowledgeable radiologist attending the patient and with the concurrence of the referring physician as well.

If the patch is removed, a specific staff member should be given responsibility for ensuring that it is replaced or repositioned.

J. Cryogen-Related Issues

1. For superconducting systems, in the event of a system quench, it is imperative that all personnel and patients be evacuated from the MR

scan room as quickly as safely feasible and that the site access be immediately restricted to all individuals until the arrival of MR equipment service personnel. This is especially so if cryogenic gases are observed to have vented partially or completely into the scan room, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. As noted in section B.3.n above, it is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, because there may still be a considerable static magnetic field present despite a quench or partial quench of the magnet [23].

2. It should be pointed out that room oxygen monitoring was discussed by the MR Blue Ribbon Panel and rejected at this time because the present oxygen monitoring technology was considered by industry experts not to be sufficiently reliable to allow continued operation during situations of power outages, etc.

K. Claustrophobia, Anxiety, Sedation, Analgesia, and Anesthesia

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR [24, 25], American Society of Anesthesiologists (ASA) [26–29], and JCAHO standards [29].

L. Contrast Agent Safety

1. Contrast agent administration issues

No patient is to be administered prescription MR contrast agents without orders from a duly licensed physician. Intravenous injection–qualified MR technologists may start and attend to peripheral IV access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area. IV-qualified MR technologists may administer FDA-approved gadolinium-based MR contrast agents via peripheral IV routes as a bolus or as a slow or continuous injection as directed by the orders of a duly licensed site physician.

Administration of these agents is to be performed according to the ACR policy. The ACR approves of the injection of contrast material and diagnostic levels of radiopharmaceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must also be prior written approval by the medical director of the radiology department or service of such individuals. Such approval process must follow established policies and procedures, and the radiologic technologists and nurses who have been so approved must maintain documentation of continuing medical education related to materials injected and to the procedures being performed [30].

2. Prior contrast agent reaction issues

a. According to the ACR *Manual on Contrast Media* [31], adverse events after intravenous injection of gadolinium seem to be more common in patients who had previous reactions to an MR contrast agent. In one study, 16 (21%) of 75 patients who had previous adverse reactions to MR contrast agents reacted to subsequent injections of gadolinium [31]. Patients with asthma also seem to be more likely to have an adverse reaction to the administration of a gadolinium-based MR contrast agent. Patients with allergies also seemed to be at increased risk (~2.0–3.7 times, compared with patients without allergies). Patients who have had adverse reactions to iodinated contrast media are more than twice as likely to have an adverse reaction to gadolinium (6.3% of 857 patients) [31].

b. At present, there are no well-defined policies for patients who are considered to be at increased risk for having an adverse reaction to MR contrast agents. However, the following recommendations are suggested: Patients who have previously reacted to one MR contrast agent can be injected with another agent if they are restudied, and at-risk patients can be premedicated with corticosteroids and, occasionally, antihistamines [31].

c. All patients with asthma, a history of allergic respiratory disorders, prior iodinated or gadolinium-based contrast reactions, etc., should be followed more closely as they are at a demonstrably higher risk of adverse reaction.

3. Renal disease, gadolinium-based MR contrast agents, and nephrogenic systemic fibrosis (NSF)

a. Overview:

It has been recently noted that over a 4-year period, 20 patients in Denmark and five in Austria developed a very rare disease that is seen only in patients with severely impaired renal function [32, 33]. Each of these patients had been administered Omniscan (gadodiamide, GE Healthcare), a gadolinium-based MR contrast agent (GBMCA), for an MR imaging or angiographic examination within a few weeks or months prior to the onset of the disease. Roughly 17,500 patients are examined using Omniscan in Denmark each year. Since January 2002, about 400 patients with severely impaired renal function had been examined, of which 20, or 5%, to whom Omniscan had been administered, eventually were diagnosed with this disease in that country.

The disease in question, originally known as nephrogenic fibrosing dermopathy (NFD) and now more widely recognized as nephrogenic systemic fibrosis (NSF), was only first observed in 1997 and formally described in 2000 [34]. It is associated with increased tissue deposition of collagen, often resulting in thickening and tightening of the skin (usually involving predominantly the distal extremities but occasionally also the trunk) and fibrosis that may involve other parts of the body, including the diaphragm, heart, lung, pulmonary vasculature, and skeletal muscles. There is no definitive cure, although some anecdotal reports exist of at least partial responses to various therapies such as plasmapheresis, extracorporeal photopheresis, and thalidomide. There are some data that suggest slowing or even reversal of the disease symptoms may accompany improvements in renal function (especially transplantation). The disease is progressive and can be fulminant in approximately 5% of cases and can even be associated with a fatal outcome. It is generally seen in middle-aged patients but has also been seen in the elderly as well as the pediatric population [35, 36]. There may be a special predilection for patients with concurrent hepatic disease, but this is not yet clearly established [37, 38].

A central registry for NSF patients is maintained at Yale University by Dr. Shawn Cowper, one of the physicians who originally described this disease [39]. At the time of this writing (1/25/07), virtually all reg-

istry cases in which records can be located have at least one known exposure to gadolinium within a few days to months prior to the development of clinical symptoms [37, verbal communication with Dr. Cowper, December 2006].

b. The association with gadolinium-based MR contrast agents (GBMCAs):

Besides the initial reports noted above, in August 2, 2006, researchers from the Copenhagen University Hospital in Denmark published in the *Journal of the American Society of Nephrology* [40] the results of their review of all 13 confirmed cases of NSF, in which they found that all 13 had received Omniscan 2–75 days (median, 25 days) prior to the development of NSF. To quote from their manuscript, "No other exposure/event than gadodiamide that was common to more than a minority of the patients could be identified. These findings indicate that gadodiamide plays a causative role in nephrogenic systemic fibrosis."

In that article, they also reported that these 13 patients with confirmed NSF were among roughly 370 severe renal disease patients whom they had tracked who had undergone gadodiamide exposure/administration for an MR examination, whereas none of > 430 patients with severe renal disease who had not received a GBMCA developed NSF.

Although this association was initially reported between Omniscan and NSF, there are now multiple submitted MedWatch cases [11] that allege that diagnoses of NSF followed intravenous administration of Magnevist (gadopentetate dimeglumine, Schering) as well as intravenous administration of OptiMARK (gadoversetamide, Mallinckrodt), which are other chelates of GBMCAs. It is clear that the vast majority (≈ 90%) of known cases at this time seem to be clearly associated with Omniscan to a degree that is out of proportion to the relative market shares for these agents [41, 42]. As of January 17, 2007, of the > 100 cases of NSF reported to the FDA MedWatch reporting system, 85 are Omniscan-associated, 21 are Magnevist-associated, six are OptiMARK-associated, none are associated with ProHance (gadoteridol, Bracco Diagnostics), and one is associated with MultiHance (gadobenate dimeglumine, Bracco Diagnostics) (although this same patient also received Omniscan 5 days after their MultiHance MR examination, and subsequently developed NSF) (personal communication, Dr. Melanie Blank, FDA, January 18, 2007). It is also important to recognize the substantial lack of scientific process inherent in the MedWatch reporting system, whose self-reported data can be used at best as general-trend-indicating and typically not for more specific analyses. Nevertheless, the data support the FDA's concern that this association may exist for the administration of other, or perhaps any of the other, FDA-approved GBMCAs and the subsequent development of NSF. Although there is evidence associating the development of NSF in renal failure patients with only some, but not all, of the FDA-approved GBMCAs to date, prudence dictates that at this time similar concerns be applied to all GBMCAs in this regard until more definitive information is forthcoming on this issue.

c. Causation?

There is a conjecture that suggests that if a causative relationship exists, it may be secondary to accumulation of the gadolinium chelate or free gadolinium in the dependent subcutaneous tissues of the lower and upper extremities (where the disease seems to most often initially manifest itself). Further, if there is free gadolinium released in any quantity, studies have suggested that it may accumulate in and bind to bone [43]. Very recent initial reports have apparently demonstrated the presence of gadolinium in the biopsies of tissues of NSF patients [44, 45]. In one control individual without NSF, no gadolinium was found using the same electron dispersion spectroscopy technique.

It should also be added that the very visualization of gadolinium in the scanning electron micrographs (SEM) noted in these two recent publications [44, 45] itself is strong evidence that dissociation of the gadolinium from its chelate has occurred. This can be related to the observation that in the process of preparing the tissue for SEM, water-soluble forms of gadolinium would have likely been removed from the specimen, leaving only the insoluble forms to precipitate out (verbal communication, Michael Tweedle, Bracco Diagnostics, January 2007, and Hanns-Joachim Weinmann, Bayer Schering Pharma, January 19, 2007). These precipitates are likely to be largely gadolinium phosphates (verbal communication, Hanns-Joachim Weinmann, January 19, 2007), but this is neither definite nor universally established.

Additionally, it has been noted by several investigators that the development of NSF seemed to most commonly (although not exclusively) follow high-dose administration of gadolinium-based MR contrast agents. This dose-response observation also suggests a possible etiologic role of these agents in the development of NSF in these patients [37].

Although a definitive causal relationship between GBMCA administration to severe renal disease patients and the development of NSF has not been absolutely established, it certainly does appear that gadolinium administration is quite likely a necessary factor in the development of NSF at this time. If a causative role is postulated or even demonstrated, it is unclear whether the causative agent is released free gadolinium, prolonged exposure to abnormally high doses of the gadolinium-plus-chelate molecule, the chelate itself, or some combination of the above with other factors that might be relatively unique to the biochemical milieu of the patient with severe renal failure. This is supported in part by the observation that in several of the publications, including the initial report from the Danish Medicines Agency [33, 37], the incidence of developing NSF in patients with severe or end-stage renal disease after being administered Omniscan appears to be roughly only 3–5%.

There are early data that suggest that elevated levels of phosphate, iron, zinc, or copper [46] or the presence of Fosrenol (lanthanum carbonate, Shire) might serve as efficient competitors for the "attention" of the chelate molecule, so to speak, and increase the concentration of free gadolinium (Gd^{3+}) in the patient, which might therefore increase the potential of the patient to develop NSF. A history of multiple prior GBMCA administrations also seems to be associated with an increased incidence of subsequent development of NSF.

d. Gadolinium toxicity:

Free gadolinium ion exists most commonly in a 3^+ charged form that inhibits those chemical processes that depend upon the influx of calcium (2^+) ions, such as cardiac and skeletal muscle, neurologic discharge, normal coagulation pathways, some enzymatic reactions, etc.

e. FDA guidance:

On December 22, 2006, the FDA issued an update [47] to their earlier June 9, 2006, public health advisory (PHA) [48]. This new

version has significantly changed from the prior one in several areas. One of these modifications includes the fact that the new version now includes wording that recommends caution in administering GBMCAs to patients with moderate to end-stage renal disease as well as consideration of providing hemodialysis treatment immediately after administration of this agent for patients in this category of renal disease who receive these agents. (The prior advisory recommended caution, especially in patients with end-stage renal disease, with glomerular filtration rates of < 15 mL/min/m^2 [48].) Quoting from this more recent advisory [47]:

> *When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.*

Average excretory rates of gadolinium were 78%, 96%, and 99% in the first to third hemodialysis sessions, respectively, in end-stage renal disease patients who received Magnevist [49]. One study has found that the mean half-life of gadodiamide is 1.3 hours in healthy volunteers, 34.3 hours in patients with a glomerular filtration rate (GFR) range of 2–10 mL/min/m^2, 2.6 hours in hemodialysis patients, and 52.7 hours in peritoneal dialysis patients [50]. It is also known that different hemodialysis membranes have been demonstrated to vary in their effectiveness at clearing the administered GBMCA [51].

It should be pointed out that virtually all present data seem to indicate that the vast majority of NSF patients to date had either severe or end-stage renal disease at the time of diagnosis or administration of the GBMCA, with most already being on dialysis. The official National Kidney Foundation staging system classifies patients with glomerular filtration rates between 30 and 59 mL/min/1.73 m^2 as having stage 3 or moderate chronic kidney disease (CKD), between 15 and 29 mL/min/1.73 m^2 as stage 4 or severe CKD, and those with GFR < 15 mL/min/1.73 m^2 or on dialysis as having stage 5 or end-stage CKD. More than one of four adults over age 70 has a GFR of < 60 mL/min/1.73 m^2, and roughly 7.7 million Americans have a GFR between 30 and 60 mL/min/1.73 m^2 [52]. Based on NHANES III 1988–1994 (the Third National Health and Nutrition Examination Survey of the CDC) [53], the prevalence of a GFR < 60 mL/min/m^2 in US adults ≥ 20 years of age was 8.0%, or more than one of every 13 adults. By age 70, the normal mean value is approximately 70 mL/min/1.73 m^2. For adults age 70 and older, the prevalence of GFR < 60 mL/min/1.73 m^2 is roughly 26%, or more than one in four. Finally, the normal GFR for neonates ≤ 8 weeks of age is < 65 mL/min/1.73 m^2 [54]. Therefore, an advisory statement worded in this manner might result in exposing patients to the potentially greater risks of hemodialysis or in withholding contrast enhancement for their studies. Since the elderly population are among the greatest users of MRI today, this advisory is especially of concern.

f. Other guidance resources:

An overview of this disease, as well as our recommendations for guidelines regarding NSF, renal disease patients, and gadolinium-based MR contrast agent administration, was accepted for publication in *Radiology* and is already available for download from *Radiology*'s online site [55].

The European Agency for the Evaluation of Medicinal Products (EMEA) has recently issued a recommendation [56] to consider the administration of Omniscan (and OptiMARK, although the latter is not licensed in Europe) as contraindicated in patients with severe renal disease (GFR < 30 mL/min/1.73m^2) or those who have had or will be undergoing a liver transplant. They also warn that for children up to 1 year of age, because their kidneys are immature, one should be most cautious about administering Omniscan (or OptiMARK). For the other non-Omniscan gadolinium-based MR contrast agents (GBMCAs), they advise simply that there is a possibility of NSF resulting with some GBMCAs in patients with severe renal disease. The European Pharmacovigilance Working Party (PhVWP) and the United Kingdom Commission on Human Medicines (CHM) do not recommend dialysis after administration of GBMCAs, even for hemodialysis patients [56].

As noted above, the FDA continues to recommend considering immediate hemodialysis for any patient with moderate, severe, or end-stage renal disease receiving any GBMCA [47].

g. Recommendations:

At this stage, the following guidelines are recommended when considering administering a GBMCA to patients with renal failure/disease:

The development of NSF in patients with renal disease has followed the administration of some, but not all, of the FDA-approved GBMCAs. To date, the development of NSF has been associated with the isolated prior administration of—especially, and clearly predominantly—Omniscan (at rates that exceed those associated with simple market share), but also Magnevist and OptiMARK. Nevertheless, it is thought to be appropriate to assume for now that a potential association might exist for all five FDA-approved gadolinium-based MR contrast agents until there are more definitive data to suspect otherwise.

At this time, no special treatment or handling is recommended for kidney disease patients with stage 1 or 2 chronic kidney disease (defined as presence of kidney damage with GFR > 90 mL/min/1.73 m^2 or GFR between 60 and 89 mL/min/1.73 m^2, respectively). The only exception to this is that patients with any level of renal disease should not receive Omniscan for their contrast-enhanced MR examinations. This is an opinion shared by others [57] and seems prudent for all renal disease patients.

Prospectively checking patient renal function, serum creatinine level, or glomerular filtration rate prior to accepting a patient for an MR imaging or angiographic examination is specifically not required. Among the reasons for this is that roughly 90% of NSF patients seem to already be on dialysis and the majority of the remainder seem to be stage 5 or stage 4. Add to this the fact that one could avoid administering any of the agents with which NSF has been most strongly associated, and the fact that even in patients with severe or end-stage renal disease the incidence of developing NSF seems to be around 3–5%. Therefore, specific prospective hematologic screening is not felt to be warranted. Instead, it is recommended that all requests for MR be prescreened, with an additional question inquiring about the presence of a history of "kidney disease or dialysis." If the disease is present but quite mild (stages 1 or 2), modification of how the study should be performed (relative to a patient with no renal disease) does not appear to be indicated except for the avoidance of Omniscan. Conversely, if the disease is present and severe or end-stage in nature, the patient will often be aware of this level of kidney disease and will likely be under

physician care for this condition. *The American Journal of Kidney Diseases* states [54]: "In general, patients with GFR <30 mL/min/1.73 m^2 should be referred to a nephrologist." Thus, selecting patients with a GFR threshold of roughly 30 mL/min/1.73 m^2 or already on dialysis (i.e., stages 4 and/or 5) as the level for which special consideration (including possibly hemodialysis) should be given, might represent a medically reasonable approach to, and compromise on, this issue. For patients with stage 3 CKD, the potential risks associated with withholding an MR imaging or angiographic examination could outweigh the potential risk of developing NSF, given the very few number of patients with putative GFR < 60 mL/min/m^2 who have been reported to have developed NSF. Further data are clearly needed to clarify the potential risk for stage 3 CKD patients given the few cases reported and the large number of patients with stage 3 CKD and who are predominantly older than age 70 who would be affected.

For all patients with stage 3, 4, or 5 kidney disease or those with acute kidney injury (AKI), it is recommended that one consider refraining from administering any GBMCAs unless a risk–benefit assessment for that particular patient indicates that the benefit of doing so clearly outweighs the potential risk(s). Similar reasoning applies equally to patients with protected regions which the gadolinium chelate might enter but from which it might not be readily cleared. An example of such a space is the amniotic fluid, in which these contrast agents can accumulate shortly after intravenous administration (personal observation and verbal communication, Emanuel Kanal, 1988).

When risk–benefit assessments warrant administration of a GBMCA to patients with stages 3–5 renal disease (moderate to end-stage) or AKI, consideration should be given to administering the lowest dose that would provide the diagnostic benefit being sought, with a half-dose, if clinically acceptable, being considered the default standard dose for such patients. The study should be monitored during its execution and prior to contrast administration to ensure that the administration of the GBMCA is still deemed necessary and indicated at that time. Postponing the examination in patients with AKI until renal function has recovered should also be considered if clinically feasible.

Standard medical practice dictates that for all patients who receive a contrast agent, the type, dose, and route of administration are to be documented in a physician order and in the report. However, patients with moderate to end-stage (stages 3–5) renal disease who are to undergo contrast-enhanced MR imaging examinations of any kind must have a written order to this effect for this agent from the radiologist approving the examination. This order must arise explicitly from the radiologist and NOT from either a referring physician or an MR imaging protocol standing order. The name of the patient, the name and specific brand of GBMCA, dose, route, and rate of administration should all be explicitly specified on the order, along with the date and signature of the requesting radiologist.

Prospective documentation of a risk–benefit assessment for each such patient is considered advisable. It is recommended that all patients identified as having moderate to end-stage (stages 3–5) kidney disease in whom a GBMCA is to be administered provide informed consent when practical, which includes a review of known risks and benefits as well as the possible availability of alternative imaging methods, if any.

As noted above, early data suggest that elevated levels of phosphate, iron, zinc, or copper might serve as efficient competitors for the "attention" of the chelate molecule [46]. These might therefore result in increased levels of free gadolinium (Gd^{3+}) ion in the patient, which might in turn increase the potential of the patient to develop NSF. Other cations such as lanthanum, now used as lanthanum carbonate (Fosrenol) for phosphorus binding in end-stage renal disease patients, could also present similar transmetallation and free gadolinium concerns. A history of multiple prior GBMCA administrations or hepatorenal disease also seems to be associated with an increased incidence of subsequent development of NSF. The existence of acidosis or active inflammatory and/or thrombotic processes as possible increased risk factors has been entertained but has not been reproducibly established at this point. This information should be taken into account during the risk–benefit assessment of each individual patient.

For administration of GBMCAs to patients on hemodialysis, the patient is to be transported to hemodialysis immediately upon the termination of the MR imaging examination. Arrangements should be made with the treating dialysis centers to provide them with as much notice as possible prior to the arrival of that patient for hemodialysis. It is recommended that hemodialysis be initiated no later than 2 hours following the administration of the GBMCA. This applies equally to emergent or urgent gadolinium chelate administration to these patients and to inpatients as well as outpatients. An additional hemodialysis session should be considered within 24 hours of this first contrast-enhanced treatment session for the reasons noted above.

For administration to patients on chronic ambulatory peritoneal dialysis (CAPD) or continuous cycler-assisted peritoneal dialysis (CCPD) (also known as automated peritoneal dialysis, or APD), there appears to be strong reason to hesitate to administer these agents. As noted above, this process of dialysis seems to be relatively ineffective at clearing the gadolinium from the body. Thus, special caution should be exercised when deciding whether a peritoneal dialysis patient should receive gadolinium-based MR contrast agents. If it is decided that they should be administered such agents, administration of the lowest reasonable dose is strongly recommended. In the past, it had been recommended that the patient avoid periods of a dry abdomen (i.e., no dialysate in the peritoneal cavity) and that the patient be advised to begin additional dialysis self-treatments or CCPD treatments immediately upon the termination of the MR examination in which the GBMCA was administered. These suggestions seemed prudent, although the efficacy of these recommendations had not been established. However, in light of the near-total apparent ineffectiveness of peritoneal dialysis at clearing the gadolinium from the body, it may well be worth considering immediate initiation of hemodialysis in peritoneal dialysis patients who receive even a low dose of a GBMCA, or not administering the agent if clinically feasible. Investigations are ongoing at this time to attempt to assess prevalence rates of NSF in peritoneal dialysis versus hemodialysis patients, although at this time it is too early for definitive conclusions.

Historically, as a result of the high atomic number associated with GBMCAs, these agents have occasionally been administered to (especially renal failure) patients in an off-label manner for such X-ray-based diagnostic tests as conventional angiography (including access angiography and fistulography) and even CT scanning. The rationale behind this practice was to avoid the administration of iodinated contrast agents to these patients and to decrease the incidence or likelihood of the development of contrast-induced nephropathy. In an attempt to prevent inadvertent GBMCA administration to renal disease patients by nonradiologists (who may at this point still not be fully aware of the issues and risks associated with GBMCAs), for now it is thought pru-

dent to ensure that all GBMCAs are to be administered only by radiologists. If there is a request for a GBMCA to be administered by a nonradiologist to a patient for an off-label use, such as intraarterial administration for vascular assessment in renal failure patients, this must be made in the form of a written order. All such requests must be prospectively reviewed and approved by either a radiologist or a pharmacist knowledgeable in the issues raised above, a risk–benefit assessment should be prospectively performed, and, where practical, informed consent should be provided by the patient.

For patients in whom a diagnosis of NSF has already been established, it might be appropriate to consider avoiding entirely any administration of a gadolinium-based MR contrast agent.

For patients not already on hemodialysis, the FDA's December 22, 2006 advisory [47] notwithstanding, the decision to initiate hemodialysis following gadolinium administration should not be taken lightly. The vast majority of NSF cases developed in patients with severe or end-stage renal disease, and most were already dialysis patients. The numbers of patients with moderate, as opposed to severe or end-stage, renal disease who have been diagnosed with NSF is exceedingly small, if they exist at all. At this time, it seems reasonable to assume that as the renal function/GFR decreases from 60 mL/min/m^2 through 30 mL/min/m^2, 15 mL/min/m^2, and below, the greater the concern and the greater the likelihood of subsequent NSF development. Therefore, we think that at the present time insufficient data exist to advise consideration for hemodialysis in this population of patients with moderate chronic kidney disease (stage 3) in the same manner or same perceived risk as those with severe or end-stage renal disease (stages 4 and 5). The risks of initiating hemodialysis must be seriously weighed against those of developing NSF in each particular case before a decision is made one way or the other. Finally, withholding clinically indicated GBMCAs can also be associated with its own risks, which should be considered in the decision-making process for all patients with kidney disease.

Should a new diagnosis of NSF be made, it is recommended that the FDA be notified through their MedWatch program (http://www.fda.gov/medwatch/) [11] or by phone (1-800-FDA-1088), and that the international NSF registry at Yale University be notified as well (http://www.icnfdr.org) [39] to ensure that each database is kept as current as possible on this rapidly changing environment.

In the weeks and months to come, it is anticipated that there will be much further study of this issue, and that more information will be forthcoming that will hopefully shed more light on this important issue [56].

M. Patients in Whom There Are or May Be Intracranial Aneurysm Clips

1. In the event that it is unclear whether a patient does or does not have an aneurysm clip in place, plain films should be obtained. Alternatively, if available, any cranial plain films, CT, or MR examination that may have taken place in the recent past (i.e., subsequent to the suspected surgical date) should be reviewed to assess for a possible intracranial aneurysm clip.
2. In the event that a patient is identified to have an intracranial aneurysm clip in place, the MR examination should not be performed until it can be documented that the type of aneurysm clip within that patient is MR safe or MR conditional. All documentation of types of implanted clips, dates, etc., *must* be in writing and signed by a licensed physician. Phone or verbal histories and histories provided by a nonphysician are not acceptable. Fax copies of operative reports, physician statements, etc. are acceptable as long as a legible physician signature accompanies the requisite documentation. A written history of the clip itself having been appropriately tested for ferromagnetic properties (and description of the testing methodology used) prior to implantation by the operating surgeon is also considered acceptable if the testing follows the deflection test methodology established by ASTM International.
3. All implanted intracranial aneurysm clips that are documented in writing to be composed of titanium (either the commercially pure or the titanium alloy types) can be accepted for scanning without any other testing.
4. All nontitanium intracranial aneurysm clips manufactured in 1995 or later for which the manufacturer's product labeling continues to claim MR compatibility may be accepted for MR scanning without further testing.
5. Clips manufactured prior to 1995 require either pretesting (according to the ASTM deflection test methodology) prior to implantation or individual review of previous MRI of the clip or brain in that particular case, if available. By assessing the size of the artifact associated with the clip relative to the static field strength on which it was studied, the sequence type, and the MRI parameters selected, an opinion may be issued by one of the site's level 2 MR attending radiologists as to whether the clip demonstrates significant ferromagnetic properties or not. Access to the MR scanner would then be based on that opinion.
6. A patient with an aneurysm clip (or other implant) may have safely undergone a prior MR examination at any given static magnetic field strength. This fact in and of itself is not sufficient evidence of the implant's MR safety and should not solely be relied upon to determine the MR safety or compatibility status of that aneurysm clip (or other implant).

   Variations in static magnetic field strength, static magnetic field spatial gradient, orientation of the aneurysm clip (or other implant) to the static magnetic field or static field gradient, rate of motion through the spatial static field gradient, etc., are all variables that are virtually impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance but may result in significant injury or death on a subsequent exposure. For example, a patient who went blind from interactions between the metallic foreign body in his retina and the spatial static fields of the MR scanner entered the magnet and underwent the entire MR examination without difficulty; he went blind only on exiting the MR scanner at the completion of the examination.
7. Barring availability of either pretesting or prior MRI data of the clip in question, a risk–benefit assessment and review must be performed in each case individually. Further, for patients with intracranial clips with no available ferromagnetic or imaging data, should the risk–benefit ratio favor the performance of the MR study, the patient or guardian should provide written informed consent that includes death as a potential risk of the MRI procedure before that patient is permitted to undergo an MR examination.

N. Patients in Whom There Are or May Be Cardiac Pacemakers or Implantable Cardioverter Defibrillators

It is recommended that the presence of implanted cardiac pacemakers or implantable cardioverter defibrillators (ICDs) be considered a rel-

ative contraindication for MRI. MRI of patients with pacemakers and ICDs ("device patients") is *not* routine. Should an MRI be considered, it should be done on a case-by-case and site-by-site basis, and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand. As of this writing, no cardiac pacing and/or defibrillating devices are labeled safe or conditionally safe for MRI scanning. Pacemaker and/or ICD leads may also present a hazard in the absence of any implant connected to them.

The protective circuitry of pacemakers and ICDs and their resistance to electromagnetic interference (EMI) has steadily improved over the years. Therefore, recently marketed ("modern") devices may be safer in the MRI environment. However, the committee eschews the term "modern" when referring to a particular device, recognizing that all devices currently marketed contain legacy components that may or may not be resistant to the forces and EMI present in the MRI suite. Future devices, unless appropriately tested and labeled as such, should not be regarded as safe for MRI simply because they are "modern" or recently manufactured.

Unexpected programming changes, inhibition of pacemaker output, failure to pace, transient asynchronous pacing, rapid cardiac pacing, the induction of ventricular fibrillation, heating of the tissue adjacent to the pacing or ICD system, early battery depletion, and outright device failure requiring replacement may all occur during MRI of patients with pacemakers or ICDs. The committee notes that multiple deaths have occurred under poorly and incompletely characterized circumstances when device patients underwent MRI. These deaths may have occurred as a result of pacemaker inhibition, failure to capture or device failure (resulting in prolonged asystole), and/or rapid cardiac pacing or asynchronous pacing (resulting in the initiation of ventricular tachycardia or fibrillation).

Ideally, the nonemergent patient should be apprised of the risks associated with the procedure and should provide prospective written informed consent prior to the initiation of MRI. While the majority of reported deliberate scans of device patients have proceeded without mishap when appropriate precautions were taken, there may be underreporting of adverse events, including deaths [58]. Thus, assignment of a risk–benefit ratio to the performance of MRI in a device patient is difficult. While the risk may be low, device patients who are considered for MRI should be advised that life-threatening arrhythmias might occur during MRI and serious device malfunction might occur, requiring replacement of the device.

Should any MRI examination be contemplated for a patient with an implanted pacemaker or ICD, it is recommended that radiology and cardiology personnel and a fully stocked crash cart be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MR study. The cardiologist should be familiar with the patient's arrhythmia history and the implanted device. A programmer that can be used to adjust the device as necessary should be readily available. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At a minimum, ECG and pulse oximetry should be used. At the conclusion of the examination, the cardiologist should examine the device to confirm that the function is consistent with its preexamination state. Follow-up should include a check of the patient's device at a time remote (1–6 weeks) after the scan to confirm appropriate function.

Should an MRI (or entry into the magnet area) be performed inadvertently on a patient with a pacemaker or ICD, the patient's cardiologist should be contacted before the patient's discharge from the MRI suite. The importance of examination of the device prior to the patient's leaving the MRI suite cannot be overstated.

O. Site Emergency Preparedness

There are many factors to consider when attempting to ensure that an MR imaging facility is adequately and appropriately prepared to handle any of several types of emergencies that might impact MR scanners of varied design types. Appendix 4 addresses these issues in some detail and provides specific guidelines to help anticipate and safeguard sites from some of the more common emergencies and disasters that might affect MR imaging facilities.

References

1. Chaljub G, Kramer LA, Johnson RF III, Singh H, Crow WN. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. *AJR* 2001; 177:27–30
2. ECRI hazard report. Patient death illustrates the importance of adhering to safety precautions in magnetic resonance environments. *Health Devices* 2001; 30:311–314
3. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology white paper on MR safety. *AJR* 2002; 178:1335–1347
4. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology white paper on MR safety: 2004 update and revisions. *AJR* 2004; 182:1111–1114
5. Shellock FG, Kanal E. Policies, guidelines and recommendations for MR imaging safety and patient management. The SMRI Safety Committee. *J Magn Reson Imaging* 1991; 1:97–101
6. Kanal E, Shellock FG. Policies, guidelines and recommendations for MR imaging safety and patient management. The SMRI Safety Committee. *J Magn Reson Imaging* 1992; 2:247–248
7. Shellock FG, Kanal E. Guidelines and recommendations for MR imaging safety and patient management. III. Questionnaire for screening patients before MR procedures. The SMRI Safety Committee. *J Magn Reson Imaging* 1994; 4:749–751
8. American College of Radiology. ACR standard for magnetic resonance imaging monograph: safety and sedation. In: *Practice guidelines and technical standards 1996*. Reston, VA: American College of Radiology, 1996
9. American College of Radiology. ACR standard for performing and interpreting magnetic resonance imaging (MRI). In: *Practice guidelines and technical standards 2000*. Reston, VA: American College of Radiology, 2000:429–433
10. Medical Device Reporting (MDR) page. Center for Devices and Radiological Health, Food and Drug Administration Website. Available at: www.fda.gov/cdrh/devadvice/351.html. Accessed February 6, 2007
11. U.S. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at: www.fda.gov/medwatch/. Accessed February 12, 2007
12. Jarvik JG, Ramsey S. Radiographic screening for orbital foreign bodies prior to MR imaging: is it worth it? *Am J Neuroradiol* 2000; 21:245–247
13. Seidenwurm DJ, McDonnell CH III, Raghaven N, Breslau J. Cost utility analysis of radiographic screening for an orbital foreign body before MR imaging. *Am J Neuroradiol* 2000; 21:426–433
14. Kanal E, Gillen J, Evans JA, Savitz DA, Shellock FG. Survey of reproductive health among female MR workers. *Radiology* 1993; 187:395–399
15. American Academy of Pediatrics Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics* 1992; 89(6 Pt 1):1110–1115
16. American Academy of Pediatrics Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and

therapeutic procedures: addendum. *Pediatrics* 2002; 110:836–838

17. American Society of Anesthesiologists. *Updated practice guidelines for sedation and analgesia by non-anesthesiologists.* Park Ridge, IL: American Society of Anesthesiologists, 2001
18. Joint Commission on the Accreditation of Healthcare Organizations. *Standards and intents for sedation and anesthesia care: comprehensive accreditation manual for hospitals.* Report no. TX 2-2. Chicago, IL: JCAHO, 2002
19. Bryan YF, Templeton TW, Nick TG, Szafran M, Tung A. Brain magnetic resonance imaging increases core body temperature in sedated children. *Anesth Analg* 2006; 102:1674–1679
20. Gandhi OP, Chen XB. Specific absorption rates and induced current densities for an anatomy-based model of the human for exposure to time varying magnetic fields of MRI. *Magn Reson Med* 1999; 41:816–823
21. Konings MK, Bartels LW, Smits HFM, et al. Heating around intravascular guidewires by resonating RF waves. *J Magn Reson Imaging* 2000; 12:79–85
22. Shellock FG. *Pocket guide to MR procedures and metallic objects: update 2001.* Philadelphia, PA: Lippincott Williams & Wilkins; 2001:147–148
23. International Electrotechnical Commission. *Medical electrical equipment. Part 2. Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. IEC 60601-2-33, ed. 2.0.* Geneva, Switzerland: IEC, 2002. (In the United States, copies of this standard can be obtained from the American National Standards Institute (ANSI), 11 W 42nd St., New York, NY 10036.)
24. American College of Radiology. ACR practice guideline for adult sedation/analgesia. In: *Practice guidelines and technical standards 2000.* Reston, VA: American College of Radiology, 2000
25. American College of Radiology. ACR practice guideline for pediatric sedation/analgesia. In: *Practice guidelines and technical standards 1998.* Reston, VA: American College of Radiology, 1998
26. American Society of Anesthesiologists. *Guidelines for non-operating room anesthetizing locations.* Park Ridge, IL: American Society of Anesthesiologists, 2001
27. American Society of Anesthesiologists. *Standards for basic anesthetic monitoring.* Park Ridge, IL: American Society of Anesthesiologists, 1986, 1998
28. American Society of Anesthesiologists. *Standards for post anesthesia care.* Park Ridge, IL: American Society of Anesthesiologists, 1988, 1994
29. Joint Commission on Accreditation of Healthcare Organizations. *Standards and intents for sedation and anesthesia care: comprehensive accreditation manual for hospitals.* Report TX. 2-2.4.1. Chicago, IL: JCAHO, 2001
30. American College of Radiology. *ACR digest of council actions.* Reston, VA: ACR, 1999:126 (Res. 1-H, 1987, 1997)
31. American College of Radiology Committee on Drugs and Contrast Media. *Manual on contrast media,* 4.1 ed. Reston, VA; American College of Radiology, 1998
32. Grobner T. Gadolinium: a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis? *Nephrol Dial Transplant* 2006; 21:1104–1108; erratum in *Nephrol Dial Transplant* 2006; 21:1745
33. Investigation of the safety of MRI contrast medium Omniscan, May 29, 2006. Danish Medicines Agency Website. Available at: www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=8931. Accessed January 25, 2007; last updated January 24, 2007
34. Cowper SE, Robin HS, Steinberg SM, Su LD, Gupta S, LeBoit PE. Scleromyxoedema-like cutaneous diseases in renal-dialysis patients. *Lancet* 2000; 356:1000–1001
35. Jain SM, Wesson S, Hassanein A, et al. Nephrogenic fibrosing dermopathy in pediatric patients. *Pediatr Nephrol* 2004; 19:467–470
36. Dharnidharka VR, Wesson SK, Fennell RS. Gadolinium and nephrogenic fibrosing dermopathy in pediatric patients. (letter) *Pediatr Nephrol* 2006 Dec 16; [Epub ahead of print]
37. Broome DR, Girguis MS, Baron PW, Cottrell AC, Kjellin I, Kirk GA. Gadodiamide-associated nephrogenic systemic fibrosis: why radiologists should be concerned. *AJR* 2007; 188:586–592
38. Maloo M, Abt P, Younan D, et al. Nephrogenic systemic fibrosis among liver transplant recipients: a single institution experience and topic update. *Am J Transplant* 2006; 6:2212–2217
39. Cowper SE. Nephrogenic fibrosing dermopathy [NFD/NSF Website]. 2001–2007. Available at: www.icnfdr.org. Accessed January 24, 2007; site last updated January 24, 2007
40. Marckmann P, Skov L, Rossen K, et al. Nephrogenic systemic fibrosis: suspected causative role of gadodiamide used for contrast-enhanced magnetic resonance imaging. *J Am Soc Nephrol* 2006; 17:2359–2362
41. Thomsen HS. Nephrogenic systemic fibrosis: a serious late adverse reaction to gadodiamide. *Eur Radiol* 2006; 16:2619–2621
42. Khurana A, Runge VM, Narayanan M, Greene JF Jr, Nickel AE. Nephrogenic systemic fibrosis: a review of 6 cases temporally related to gadodiamide injection (Omniscan). *Invest Radiol* 2007; 42:139–145
43. White GW, Gibby WA, Tweedle MF. Comparison of Gd (DTPA-BMA) (Omniscan) versus Gd (HP-DO3A) (ProHance) relative to gadolinium retention in human bone tissue by inductively coupled plasma mass spectroscopy. *Invest Radiol* 2006; 41:272–278
44. High WQ, Ayers RA, Chandler J, Zito G, Cowper SE. Gadolinium is detectable within the tissues of patients with nephrogenic systemic fibrosis. *J Am Acad Dermatol* 2007; 56:21–26
45. Boyd AS, Zic JA, Abraham JL. Gadolinium deposition in nephrogenic fibrosing dermopathy. *J Am Acad Dermatol* 2007; 56:27–30
46. Idee J-M, Port M, Raynal I, Schaefer M, Grenier SL, Corot C. Clinical and biological consequences of transmetallation induced by contrast agents for magnetic resonance imaging: a review. *Fundam Clin Pharmacol* 2006; 20:563–576
47. Food and Drug Administration Center for Drug Evaluation and Research. Public health advisory. Update on magnetic resonance imaging (MRI) contrast agents containing gadolinium and nephrogenic fibrosing dermopathy. Available at: www.fda.gov/cder/drug/advisory/gadolinium_agents_20061222.htm. Accessed February 20, 2007; last updated December 22, 2006
48. U.S. Food and Drug Administration Website. Public health advisory. Gadolinium-containing contrast agents for magnetic resonance imaging (MRI): Omniscan, OptiMARK, Magnevist, ProHance, and MultiHance. Available at: http://www.fda.gov/cder/drug/advisory/gadolinium_agents.htm. Accessed August 10, 2006
49. Okada S, Katagiri K, Kumazaki T, Yokoyama H. Safety of gadolinium contrast agent in hemodialysis patients. *Acta Radiol* 2001; 42:339–341
50. Joffe P, Thomsen HS, Meusel M: Pharmacokinetics of gadodiamide injection in patients with severe renal insufficiency and patients undergoing hemodialysis or continuous ambulatory peritoneal dialysis. *Acad Radiol* 1998; 5:491–502
51. Ueda J, Furukawa T, Higashino K, et al. Permeability of iodinated and MR contrast media through two types of hemodialysis membrane. *Eur J Radiol* 1999; 31:76–80
52. The National Kidney Foundation Kidney disease outcomes quality initiative. National Kidney Foundation Website. Available at: http://www.kidney.org/Professionals/kdoqi/. Accessed February 12, 2007
53. Centers for Disease Control and Prevention, National Center for Health Statistics Website. Third National Health and Nutrition Examination Survey (NHANES III), 1988–94. Available at: www.cdc.gov/nchs/products/elec_prods/subject/nhanes3.htm. Accessed February 8, 2007
54. [No authors indicated] Part 4. Definition and classification of stages of chronic kidney disease. *Am J Kidney Dis* 2002; 39[suppl 1]:S46–S75; doi:10.1053/ajkd.2002.30943
55. Kuo PH, Kanal E, Abu-Alfa AK, Cowper SE. Gadolinium-based MR contrast agents and nephrogenic systemic fibrosis. *Radiology* 2007 Jun 9 [Epub ahead of print]. Available at: http://radiology.rsnajnls.org/cgi/content/short/2423061640v1?rss=1. Accessed February 20, 2007

56. Medicines and Healthcare products Regulatory Agency Website. Nephrogenic systemic fibrosis (NSF) and gadolinium-containing MRI contrast agents: 7 February 2007. Available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2030229&ssTargetNodeId=221. Accessed February 20, 2007
57. Thomsen HS. European Society of Urogenital Radiology guidelines on contrast media application. *Curr Opin Urol* 2007; 17:70–76
58. Bartsch C, Inrich W, Risse M, Weiler G. Unexpected sudden death of pacemaker patients during or shortly after magnetic resonance imaging (MRI). In: *XIX Congress of International Academy of Legal Medicine*. IALM: Milan, Italy, 3–6 September 2003:174 (Abstract No. 114)

Additional Sources

1. Luechinger R, Zeijlemaker VA, Pedersen EM, et al. In vivo heating of pacemaker leads during magnetic resonance imaging. *Eur Heart J* 2005; 26:376–383
2. Nitz WR, Brinker G, Diehl D, Frese G. Specific absorption rate as a poor indicator of magnetic resonance-related implant heating. *Invest Radiol* 2005; 40:773–776
3. Nguyen UD, Brown SJ, Chang IA, et al. Numerical evaluation of heating of the human head due to magnetic resonance imaging. *IEEE Transactions on Biomedical Engineering* 2004; 51:1301–1309
4. Nyenhuis JA, Park SM, Kamondetdacha R, et al. MRI and implanted medical devices: basic interactions with an emphasis on heating. *IEEE Transactions on Device and Materials Reliability* 2005; 5:467–480
5. Shellock FG, Fieno DS, Thomson LJ, Talavage TM, Berman DS. Cardiac pacemaker: in vitro assessment at 1.5 T. *Am Heart J* 2006; 2:436–443
6. Yeung CJ, Susil RC, Atalar E. RF safety of wires in interventional MRI: using a safety index. *Magn Reson Med* 2002; 47:187–193
7. Shellock FG, Begnaud J, Inman MD. Vagus nerve stimulation therapy system: in vitro evaluation of magnetic resonance imaging-related heating and function at 1.5 and 3 Tesla. *Intermodulation* 2006; 9:204–213
8. Inrich W, Inrich B, Bartsch C, et al. Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005; 7:353–365
9. Loewy J, Loewy A, Kendall EJ. Reconsideration of pacemakers and MR imaging. *RadioGraphics* 2004; 24:1257–1268
10. Luechinger R, Duru F, Candinas R, Boesiger P. Safety considerations for magnetic resonance imaging of pacemaker and ICD patients [in German]. *Herzschrittmachertherapie und Elektrophysiologie* 2004; 15:73–81
11. ASTM International. *Terminology of symbols and definitions relating to magnetic testing*, A 340. West Conshohocken, PA: *ASTM International*, 2003:1–16
12. ASTM International. *Specification for the requirements and disclosure of self-closing aneurysm clips*, F 1542. West Conshohocken, PA: *ASTM International*, 2000:1–3
13. ASTM International. *Test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment*, F 2052. West Conshohocken, PA: *ASTM International* 2002: 1–6
14. ASTM International. *Test method for evaluation of MR image artifacts from passive implants*, F 2119. West Conshohocken, PA: *ASTM International*, 2001:1–3
15. ASTM International. *Test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging*, F 2182. West Conshohocken, PA: *ASTM International*, 2002:1–8
16. ASTM International. *Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance environment*, F 2213. West Conshohocken, PA: *ASTM International*, 2004:1–7

Appendices 1–4 appear on the following pages.

APPENDIX 1: Personnel and Zone Definitions

PERSONNEL DEFINITIONS

Non-MR Personnel

Patients, visitors, or facility staff who do not meet the criteria of level 1 or level 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work in Zone III will be referred to as level 1 MR personnel (e.g., MRI department office staff and patient aides).

Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to as level 2 MR personnel (e.g., MRI technologists, radiologists, and radiology department nursing staff).

ZONE DEFINITIONS

Zone I

This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

Zone II

This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III (see below). Typically, the patients are greeted in Zone II and are not free to move throughout Zone II at will, but rather are under the supervision of MR personnel. It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.

Zone III

This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the particular environment of the MR scanner. These interactions include, but are not limited to, those with the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel.

Zone IV

This area is synonymous with the MR scanner magnet room itself. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III.

Non-MR personnel should be accompanied by, or under the immediate supervision of and visual contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions.

Level 1 and 2 MR personnel may move freely about all zones.

APPENDIX 2: MR Facility Safety Design Guidelines

The goal of MR safety is to prevent harm to patients, though an MR facility cannot simply adopt one or two interventions and hope to successfully attain this objective. According to safety and human factors engineering principles, multiple safety strategies must be adopted to be effective. This approach is sometimes termed "defense in depth." The safety strategies outlined in the main body of this Guidance Document for MR Safe Practices include, for instance, policies that restrict personnel access, specialized training and drills for MR personnel, and warning labels for devices to be brought into Zone IV regions.

Along with these people-oriented strategies of policies and training, organizations need also to adopt the strategies of safety-oriented architectural and interior design. These design elements can support the other safety strategies by making them easier or more obvious to follow. The architectural enhancements described herein add one or more strong barriers to enhance "defense in depth."

This appendix includes descriptions of architectural and interior design recommendations organized around the many MR suite functional areas. Note that a facility's design can encourage safety and best practices by improving the flow of patients, various health care personnel, and equipment and devices, and not just by preventing MR unsafe items from becoming missiles, or screening out patients with hazardous implanted devices.

Placing design elements strategically in a suite layout such that the element supports best-practice work flow patterns will increase compliance with safer practices. For example, having a private area for patient screening interviews will make it more likely the patients will disclose sensitive types of implants. Another example of designing for safety is to include dedicated space and temporary storage for MR Unsafe equipment (e.g., ferromagnetic IV poles, transport stretchers) out of direct sight and away from people flow patterns.

Effective and safe MRI suites must balance the technical demands of the MR equipment with local and state building codes, standards of accrediting bodies, clinical and patient population needs, payor requirements, and a collage of civil requirements from the Health Insurance Portability and Accountability Act (HIPAA) to the Americans with Disabilities Act (ADA).

In an effort to better match appropriate facility design guidelines with levels of patient acuity and care, the ACR MR Safety Committee is currently developing level designations for MRI facilities in conjunction with the efforts of committees from other societies and organizations. These will address customization of requirements for sites with varying anticipated patient care sedation, anesthesia, and/or interventional activities.

While it would be desirable to provide a universal MRI suite safety design, the variables are too numerous to adequately address in a single template. The following MRI Facility Safety Design Guidelines provide information in support of planning, design, and construction of MR facilities, including updates to existing MR facilities, which enhance the safety of patients, visitors, and staff. This information is intended to supplement and expand upon patient safety guidance provided throughout the ACR Guidance Document for MR Safe Practices.

1. MR Equipment Vendor Templates

Design templates provided by MR equipment manufacturers are invaluable in developing suites that meet the minimum technical siting requirements for the specific equipment. Vendor design templates, however, typically depict only the control and equipment rooms, in addition to the magnet room, Zone IV.

Patient/family waiting, interview areas, physical screening/changing areas, access controls, storage, crash carts, induction, medical gas services, holding areas for patients after screening, infection control provisions, and interventional applications, among many other issues, are not addressed in typical vendor-provided drawings. These issues are left to facility owners, operators, and their design professionals to resolve. The guidance which follows is designed to address many of these issues which directly impact safety within the MR suite.

2. Patient Interview/Clinical Screening Areas (Zone II)

Reviewing the patient Safety Screening Form and the MR Hazard Checklist requires discussing confidential personal information. To facilitate full and complete patient disclosure of their medical history, this clinical screening should be conducted in an area which provides auditory and visual privacy for the patient. Facilities should prospectively plan for electronic patient medical records, which are useful in clinical screening, and should provide access to records in the MR suite in support of clinical patient screening.

Clinical screening of inpatients may be completed in the patient room for hospital-based MR facilities. However, all screenings are to be double-checked and verified by appropriately trained MR personnel before MR examination.

3. Physical Screening and Patient Changing/Gowning Rooms (Zone II)

All persons and objects entering Zone III should be physically screened for the presence of ferromagnetic materials which, irrespective of size, can become threats in proximity to the MR scanner. A location should be provided for patients in which they may change out of their street clothes and into a facility-provided gown or scrubs, if or as deemed appropriate. For those facilities that either do not provide space for, or do not require, patient changing, the facility must provide alternative means of identifying and removing items that the patient may have brought with them that might pose threats in the MR environment.

A high-strength handheld magnet is a recommended tool to evaluate the gross magnetic characteristics of objects of unknown composition. Magnetic strength for these permanent magnets falls off quickly as one moves away from the face of the magnet. Thus, these may not demonstrate attraction for ferromagnetic components which are not superficially located or cannot for whatever reason be brought into close proximity with the surface of this handheld magnet.

Ferromagnetic detection systems have been demonstrated to be highly effective as a quality assurance tool, verifying the successful screening and identifying ferromagnetic objects which were not discovered by conventional screening methods. It is recommended that new facility construction anticipate the use of ferromagnetic detection screening in Zone II and provide for installation of the devices in a location which facilitates use and throughput. Many current ferromagnetic detection devices are capable of being positioned within Zone III, even at the door to the magnet room; however, the recommended use of ferromagnetic detection is to verify the screening of patients before they pass through the controlled point of access into Zone III.

Physical screening of patients should consist of removal of all jewelry, metallic or ferromagnetic objects, onplants, and prostheses (as indicated by manufacturer's conditional use requirements and physician instructions) and either having patients change out of their street clothes into facility-provided gowns or scrubs or thorough screening of street clothes, including identifying the contents of pockets and the composition of metallic fibers, fasteners, and reinforcing.

4. Transfer Area and Ferrous Quarantine Storage (Zone II)

Patients arriving with wheelchairs, walkers, portable oxygen, and other appliances that may be unsafe in the MR environment should be provided by the facility with appropriate MR safe or MR conditional appliances. An area should be provided to transfer the patient from unsafe appliances to ones appropriate to the MR environment. Unsafe appliances brought by the patient should be secured in a "ferrous quarantine" storage area, distinct from storage areas for MR safe and MR conditional equipment, and ideally locked out of sight. Patient belongings should be retrieved from the ferrous quarantine only when discharging the patient to whom the objects belong.

5. Access Control (Zone III and Zone IV)

Means of physically securing and restricting access to Zone III from all adjacent areas must be provided. Independent access into Zone III must be limited to only appropriately trained MR personnel.

6. Patient Holding (Zone III)

Depending upon facility capacity and patient volume, it may be advisable to provide a postscreening patient holding area. Zone III holding areas should be equipped and appointed to prevent patient exit and subsequent reentry. This will help prevent the inadvertent—or even intentional—introduction of unscreened objects and personnel.

Many multitechnique radiology facilities combine patient holding and/or induction areas for patients undergoing different types of imaging examinations. This presents safety challenges when, for example, patients scheduled to undergo CT are held in a patient holding area shared by postscreening MR patients. As CT patients would not typically be screened for MR contraindications or ferrous materials, this poses risks to both the CT patient with a contraindicated implant and to those in the MRI Zone IV should an unscreened individual inadvertently enter with a ferrous object or implant.

Unless all persons in patient holding areas used for postscreening MR patients are screened for MRI, the practice of shared patient holding areas

between MR and other techniques is discouraged. Ultimately it is the responsibility of trained MR staff to verify the screening of any commingled patient prior to permitting them to enter Zone III and Zone IV.

In all MR facilities, Zone III is required to be secured and access limited to only MR personnel and successfully MR prescreened non-MR personnel accompanied by MR personnel. Ideally, facilities should be designed so that patients undergoing other techniques are not commingled with postscreening MR patients.

7. Lines of Sight and Situational Awareness (Zone III)

Trained MR personnel are arguably the single greatest safety resource of MR facilities. These individuals should be afforded visual control over all persons entering or exiting Zone III or Zone IV. The technologist seated at the MR operator console should therefore be able to view not only the patient in the MR scanner but also the approach and entrance into Zone IV. When practical, suites should also be prospectively designed to provide a view from the MR operator's console to patient holding areas. If this cannot be satisfactorily achieved by direct line of sight, remote video viewing devices are an acceptable substitute toward accomplishing this objective.

The technologist at the console should also be provided with a view to induction and recovery areas within the MR suite, as applicable.

8. Emergency Resuscitation Equipment (Zone II or Zone III)

Because of risks associated with contrast agents, sedation, anesthesia, and even the frail health of patients undergoing MR examinations, it is advised that each facility have appropriate provisions for stabilization and resuscitation of patients.

It is recommended that crash carts and emergency resuscitation equipment be stored in a readily accessible area in either Zone II or Zone III. This emergency resuscitation equipment is to be appropriately labeled and also tested and verified as safe for usage in MR environment for the anticipated conditions of usage.

MR facilities should maintain a supply of emergency medications to treat adverse reactions to administered contrast agents.

MR facilities providing care to patients who require clinical support during the MR examination should have emergency response equipment and personnel, trained in MR safety issues as well as trained to respond to anticipatable adverse events, readily available to respond to patient adverse events or distress in the MR arena.

9. Fringe Magnetic Field Hazards (Zone III)

For many MR system installations, magnetic fringe fields which project beyond the confines of the magnet room superimpose potential hazards on spaces which may be outside the MR suite, potentially on levels above or below the MR site and perhaps even outside the building. Facilities must identify all occupyable areas, including those outside the MR suite (including rooftops, storage areas, mechanical closets, etc.) which are exposed to potentially hazardous magnetic fringe field strengths. Areas of potential hazard must be clearly identified, and access to these areas must be restricted, just as they would be within the MR suite.

10. Cryogen Safety (Zone IV)

Liquid helium and liquid nitrogen represent the most commonly used cryogens in MR environments. The physical properties of these cryogenic liquids present significant potential safety hazards. If exposed to room air, these cryogenic liquids will rapidly boil off and expand into a gaseous state. This produces several potential safety concerns, including:

- Asphyxiation is a possibility as cryogenic gases replace oxygenated air.
- Frostbite may occur at the exceedingly low temperatures of these cryogenic liquids.
- Fire hazards can exist in the unlikely event of a quench, especially if some of the cryogenic gases escape into the magnet room/Zone IV.
- Hyperbaric pressure considerations within Zone IV can rarely exist in the unlikely event of a quench in which some of the cryogenic gases escape into the magnet room/Zone IV.

a. Cryogen Fills

Though contemporary superconducting magnets require cryogen refills only infrequently, there is still almost always the need to periodically bring hundreds of liters of liquid cryogen to the magnet. It is because of the risks to persons near the magnet and storage/transport dewars that transfill operations should be undertaken with great care and only by appropriately trained personnel.

- Dewars containing cryogenic liquids should never be stored inside an MRI facility or indeed any enclosed facility unless in a facility specifically designed to manage the associated pressure, temperature, and asphyxiation risks.
- A cryogen transfill should never be attempted by untrained personnel or even with any unnecessary personnel in attendance, including MR personnel staff and patients, within Zone IV.
- Cryogen transfills should only be performed with appropriate precautions in place to prevent pressure entrapment and asphyxiation.

b. Magnet Room Cryogen Safety

For most MRI systems, if the magnet quenches, the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area. However, there have been documented failures of cryogen vent/quench pipe assemblies which have led to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room/Zone IV. The thermal expansion of the cryogens, if released into the magnet room, can positively pressurize the magnet room and entrap persons inside until such time as the pressure is equalized.

The following recommended MRI suite design and construction elements reduce patient and staff risks in the unlikely event of a quench in which the cryogen vent pathway (quench pipe) ruptures or leaks into Zone IV:

- All magnet rooms/Zone IV regions for superconducting magnets should be provided with an emergency exhaust pathway. The emergency exhaust grille is to be located in the ceiling opposite the entrance to the magnet room (Zone IV) door. At this location, when activated in the unlikely event of a quench breach, the exhaust fan is positioned to draw the vaporous cloud of cryogenic gas away from the door providing exit from the magnet room.
- Many MR manufacturers are now requiring that magnet rooms for superconducting magnets also be provided with an additional form of passive pressure relief/pressure equalization to minimize the risks of positive-pressure entrapment. Designs for passive pressure relief mechanisms should follow design criteria similar to those of cryogen vent pathway and active exhaust, including discharge to a protected area, as described in section 10.c below.

Some MR facilities are constructed without open waveguides or glass observation windows to Zone IV regions. In these facilities, the potential risks of entrapment are even greater and may warrant an additional degree of attention in this regard.

While it can provide a degree of redundancy, it should be noted that, even with an exhaust fan, designing the door to Zone IV to swing out-

ward is not, by itself, an appropriate means of pressure relief. In a severe positive-pressure situation, unlatching an outward-swinging door might permit the door to burst open with tremendous pressure, potentially injuring person(s) opening the door. If employed as the only means of pressure equalization, an outward-swinging door may actually introduce new hazards to any staff person attempting to open the door to a pressurized magnet room from the outside.

Similarly, though it has proven effective in life-threatening situations, breaking a control window should not be advocated as a primary means of relieving/equalizing Zone IV pressure in a quench situation. It should be noted that the current construction of many RF-shielded observation windows is such that breaking the window would be very difficult, further diminishing that as a viable means of pressure relief.

Once provided with appropriate pressure equalization and emergency exhaust, magnet room door swing direction and design should be left to the discretion of a facility and their design professionals.

c. Cryogen Vent Pathway

Obstructions, inappropriate pipe materials, insufficient pipe caliber and/or length, or faulty connections in the length of the cryogen vent pathway can cause failure between the magnet and the point of discharge. An evaluation of the current cryogen vent piping/ducting assembly is recommended to help identify and correct potential weaknesses that could potentially fail in a quench. Facilities are advised to evaluate the design and inspect the construction of their cryogen vent system.

Because minimum design requirements for some cryogen vent systems have been revised by magnet system vendors, facilities should obtain current standards from the original equipment manufacturers to use in evaluating their cryogen vent assembly and not rely on original siting requirements.

Beyond the assessment of the current construction of the cryogen vent system, it is prudent for MRI facilities:

- To inspect cryogen vent systems at least annually, identifying stress or wear of pipe sections and couplings, loose fittings and supports, or signs of condensation or water within the cryogen vent pathway, which may indicate a blockage.
- Following any quench of a superconducting magnet, to conduct a thorough inspection of the cryogen vent system, including pipe sections, fittings, couplings, hangers, and clamps, prior to returning the magnet to service.

Because obstructions or occlusions of the cryogen vent can increase the likelihood of rupture in a quench event, facilities should ensure that:

- The discharge point has an appropriate weatherhead that prevents horizontal, wind-driven precipitation from entering, collecting, or freezing in the quench exhaust pipe.
- The discharge point is high enough off the roof or ground surface that snow or debris cannot enter or occlude the pipe.
- The discharge is covered by a material having sufficiently small openings to prevent birds or other animals from entering the quench pipe, while not occluding cryogenic gaseous egress in a quench situation.

Facilities that discover failings in any of these basic protections of the cryogen discharge point should immediately take additional steps to verify the patency of the cryogen vent and provide the minimum current discharge protections recommended by the original equipment manufacturer.

To protect persons from cryogen exposure at the point of discharge:

- At the point of cryogen discharge, a quench safety exclusion zone with a minimum clear radius of 25 ft (8 m) should be established and clearly marked with surface warnings and signage.
- The quench safety exclusion zone should be devoid of serviceable equipment, air intakes, operable windows, or unsecured doors that either require servicing or offer a pathway for cryogenic gasses to reenter the building.
- Persons who must enter this quench safety exclusion zone, including incidental maintenance personnel and contractors, should be permitted to do so only after receiving specific instruction on quench risks and response.

11. MR Conditional Devices (Zone IV)

The normal or safe operation of many medical devices designed for use in the MR environment may be disrupted by exposure to conditions exceeding the device's conditional rating threshold. It is advisable for MR facilities to identify the maximum conditional rating for static field and spatial gradient exposure for each MR Conditional device that may be brought into Zone IV. For prospective installations, it is recommended that the location of critical isogauss line(s) be identified for MR Conditional equipment and devices used within the MR suite and delineated on the floor and walls of the magnet room to aid in the positioning and safe and effective operation of said equipment.

All MR facilities should evaluate all MR Conditional patient monitoring, ventilators, medication pumps, anesthesia machines, monitoring devices, biopsy, and other devices and equipment which may be brought into the magnet room for magnetic field tolerances. Facilities should consider providing physical indications of critical gauss lines in the construction of the magnet room to promote the safe and effective use of MR Conditional equipment, as appropriate.

12. Infection Control (Zone IV)

Because of safety concerns regarding incidental personnel within the MR suite, restricting housekeeping and cleaning personnel from Zone III and/or Zone IV regions may give rise to concerns about the cleanliness of the MR suite. Magnet room finishes and construction details should be designed to facilitate cleaning by appropriately trained staff with nonmotorized equipment. Additionally, as the numbers of MR-guided procedures and interventional applications grow, basic infection control protocols, such as seamless floorings, scrubbable surfaces, and hand-washing stations, should be considered.

13. Limits of Applicability and Recommended Design Assistance

The facility design issues identified in this document address only general safety design issues for MRI suites. There are a multitude of site-specific and magnet-specific operational and technical design considerations relevant to MR facility design and construction that are not addressed in these guidelines. These issues include, but are not limited to, patient acuity, staff access, technique conflicts, vibration sensitivity, throughput and efficiency, HIPAA considerations, magnetic contamination, sound transmission, magnet shim tolerances, shielding design, moving metal interferences, MR equipment upgrades, electromagnetic interference, and many others.

In addition to incorporating the guidance from this document, a facility would be well advised to seek expert assistance in the planning and design of MRI and multitechnique radiology suites.

APPENDIX 3: Safety Screening Form, MR Hazard Checklist, and Patient Instructions

SAFETY SCREENING FORM FOR MAGNETIC RESONANCE (MR) PROCEDURES

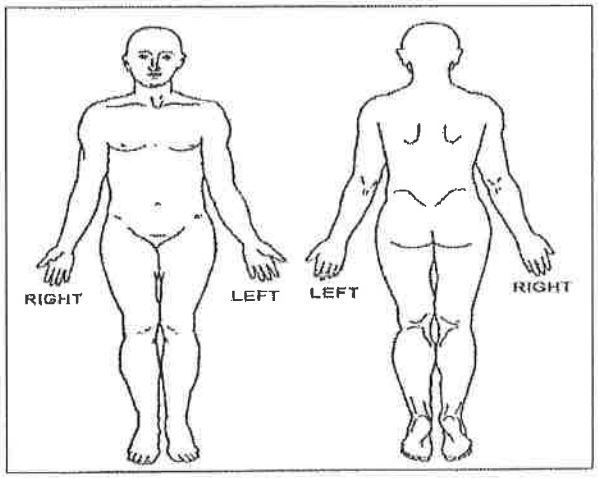
Date_____
Name (first middle last)_____
Female [ ] Male [ ] Age_____ Date of Birth_____
Height_____ Weight_____
Why are you having this examination (medical problem)?
_____

YES NO
Have you ever had an MRI examination before and had a problem?
____ ____
If yes, please describe_____
Have you ever had a surgical operation or procedure of any kind?
____ ____
If yes, list all prior surgeries and approximate dates:
_____
_____
Have you ever been injured by a metal object or foreign body (e.g., bullet, BB, shrapnel)?
____ ____
If yes, please describe_____
_____
Have you ever had an injury from a metal object in your eye (metal slivers, metal shavings, other metal object)?
____ ____
If yes, did you seek medical attention?_____
If yes, describe what was found_____
Do you have a history of kidney disease, asthma, or other allergic respiratory disease?
____ ____
Do you have any drug allergies?
____ ____
If yes, please list drugs_____
_____
Have you ever received a contrast agent or X-ray dye used for MRI, CT, or other X-ray or study?
____ ____
Have you ever had an X-ray dye or magnetic resonance imaging (MRI) contrast agent allergic reaction?
____ ____
If yes, please describe_____
_____
Are you pregnant or suspect you may be pregnant?
____ ____
Are you breast feeding?
____ ____
Date of last menstrual period_____ Post-menopausal?_____

MR Hazard Checklist

Please mark on the drawing indicating the location of any metal inside your body or site of surgical operation.

The following items may be harmful to you during your MR scan or may interfere with the MR examination. You must provide a "yes" or "no" for every item. Please indicate if you have or have had any of the following:



YES NO
____ ____ Any type of electronic, mechanical, or magnetic implant
Type_____
____ ____Cardiac pacemaker
____ ____Aneurysm clip
____ ____Implantable cardiac defibrillator
____ ____Neurostimulator
____ ____Biostimulator
Type_____
____ ____Any type of internal electrodes or wires
____ ____Cochlear implant
____ ____Hearing aid
____ ____Implanted drug pump (e.g., insulin, baclofen, chemotherapy, pain medicine)
____ ____Halo vest
____ ____Spinal fixation device
____ ____Spinal fusion procedure
____ ____Any type of coil, filter, or stent
Type_____
____ ____Any type of metal object (e.g., shrapnel, bullet, BB)
____ ____Artificial heart valve
____ ____Any type of ear implant
____ ____Penile implant
____ ____Artificial eye
____ ____Eyelid spring

Safe MR Practices

____ ____Any type of implant held in place by a magnet
Type_____
____ ____Any type of surgical clip or staple
____ ____Any IV access port (e.g., Broviac, Port-a-Cath, Hickman, PICC line)
____ ____Medication patch (e.g., nitroglycerine, nicotine)
____ ____Shunt
____ ____Artificial limb or joint
What and where_____
____ ____Tissue expander (e.g., breast)
____ ____Removable dentures, false teeth, or partial plate
____ ____ Diaphragm, IUD, pessary
Type_____
____ ____Surgical mesh
Location_____
____ ____Body piercing
Location_____
____ ____Wig, hair implants
____ ____Tattoos or tattooed eyeliner
____ ____Radiation seeds (e.g., cancer treatment)
____ ____Any implanted items (e.g., pins, rods, screws, nails, plates, wires)
____ ____Any hair accessories (e.g., bobby pins, barrettes, clips)
____ ____Jewelry
____ ____Any other type of implanted item
Type_____

Instructions for the Patient

1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination since some patients may find the noise levels unacceptable, and the noise levels may affect your hearing.
2. Remove all jewelry (e.g., necklaces, pins, rings).
3. Remove all hair pins, bobby pins, barrettes, clips, etc.
4. Remove all dentures, false teeth, partial dental plates.
5. Remove hearing aids.
6. Remove eyeglasses.
7. Remove your watch, pager, cell phone, credit and bank cards, and all other cards with a magnetic strip.
8. Remove body piercing objects.
9. Use gown, if provided, or remove all clothing with metal fasteners, zippers, etc.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form, and I have had the opportunity to ask questions regarding the information on this form.

Patient signature_____
MD/RN/RT signature_____
Date_____
Print name of MD, RN, RT_____

For MRI Office Use Only

Patient Name_____
Patient ID Number_____
Referring Physician_____
Procedure_____
Diagnosis_____
Clinical History_____

Hazard Checklist for MRI Personnel

YES NO
____ ____Endotracheal tube
____ ____Swan-Ganz catheter
____ ____Extraventricular device
____ ____Arterial line transducer

YES NO
____ ____Foley catheter with temperature sensor and/or metal clamp
____ ____Rectal probe
____ ____Esophageal probe
____ ____Tracheotomy tube
____ ____Guidewires

APPENDIX 4: MR Facility Emergency Preparedness Guidelines

Health care facilities have a unique obligation to minimize the disruption from disasters and hasten their ability to restore critical patient care services when interrupted.

Those charged with the operation of MRI facilities have the added complexities of protecting not only the staff and structure, but also the equipment, which may be extraordinarily sensitive to changes in its environment, including vibration, power supply, and water damage.

In the fall of 2005, many watched as Hurricanes Katrina and Rita devastated vast swathes of the U.S. Gulf Coast. Those facilities which were well prepared for the damage, loss of power, and other failures of infrastructure fared far better than those that that were not.

Even those not in the likely path of future Gulf hurricanes may have to contend with earthquakes, tornadoes, fires, ice storms, snowstorms, or blackouts, at some point. Particularly those involved in providing patient care should look to how we will provide care at the times when it is most widely and desperately needed. We may find that, while individuals are willing, the facilities, equipment, and infrastructure required to provide clinical care have not been adequately protected.

1. Water Damage

Whether from roof failure, burst pipes, storm surge, or rising rivers, every facility has the potential for water damage to equipment and facilities. Damage can range from inconveniences cured by a couple of hours with a wet–dry vacuum to flooding of equipment electronics. It takes only a small quantity of water in contact with an MRI scanner to incapacitate or destroy the equipment.

To keep leaking roofs, burst pipes, or other overhead damage from dousing MRI equipment, it is recommended that facilities prepare by covering gantries and equipment with sturdy plastic, taped in place, when water damage is an anticipated possibility. To keep processors and gradient cabinets from becoming swamped in a flood situation, electronics that can be lifted off the ground should be moved as far off the floor as possible. RF shields, particularly the floor assembly, may be significantly damaged and need to be replaced in a flood situation if they are not designed to be protected against water damage.

During the 2005 hurricanes, many hospitals and imaging facilities that had emergency generators to help restore power discovered that their sites had generators, or other critical supplies, in basements or other low-lying areas that were flooded. Facilities should evaluate risks from water damage and assess their preparations for failure of the building enclosure as well as the potential for a flood situation.

2. Structural Damage

MRI presents a particular challenge with structural failure. Although unlikely with current magnet systems, vibrations from seismic events do have the potential to initiate a quench of the magnet system. Structural damage or motion may also damage the RF shield enclosure, potentially degrading image quality until the shield is repaired.

3. Power Outage

Without electrical power to the vacuum pump/cold head to keep the cryogen within a superconducting MRI magnet liquefied, the cryogen will begin to boil off at an accelerated rate. Depending upon cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench.

At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gasses. This poses a safety risk to anyone near the discharge and runs a small but finite risk of potentially permanently damaging the magnet coils.

However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption.

Temporary electrical power may be provided either through on-site or portable generators. Cogeneration, or generating one's own electricity all the time, may not be economically feasible for smaller or stand-alone sites but is increasingly appealing to hospitals for a number of reasons, with emergency capacity being only one.

4. Quench

During the 2005 hurricanes, facilities, fearing extensive damage to their MRI systems from water or protracted power outages, manually initiated preemptive quenches. Under the best circumstances, a quench subjects a magnet to a change of 500°F (260°C) thermal shock within a few dozen seconds, which can cause major physical damage. Rarely, it is possible for the venting cryogenic gases to breach the quench tube and cause significant damage to the magnet room and/or jeopardize the safety of those in the vicinity. At one New Orleans area facility that elected to preemptively quench its magnets, the quench tube reportedly failed and the pressure from the expanding cryogen blew out the control room radiofrequency window (personal communication, Tobias Gilk, October 2005).

Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in nonemergent situations only after verifying the function of emergency exhaust systems, verifying or providing means of pressure relief, and performing a preliminary visual inspection of the cryogen vent pipe as it leaves the MR unit to check for signs of water or ice inside the pipe (including water leaking from fittings or condensation forming on vent pipe sections).

5. Fire and Police

Though very infrequent, MR suites have been the scene of emergencies requiring fire and/or police response. While it is quite likely this will be the first time many of the responders have been to an MR suite, this should not be the first time that responding organizations have been introduced to the safety issues for MR. Sites are encouraged to invite police and fire representatives to presentations on MR safety and to provide them with facility tours.

6. Code

In the event that a person within the MR suite should require emergency medical attention, it is imperative that those responding to a call for assistance are aware of, and comply with, MR safety protocols. This includes nurses, physicians, respiratory technicians, paramedics, security personnel, and others.

The impulse to respond immediately must be tempered by an orderly and efficient process to minimize risks to patients, staff, and equipment. This requires specialized training for code teams and, as with fire and police responses, clear lines of authority for screening, access restrictions,

and quench authority. Full resuscitation of patients within Zone IV is complicated by the inability to accurately interpret electrocardiographic data. Furthermore, this may place all within Zone IV at risk of injury from ferromagnetic objects which may be on, within, or brought into Zone IV by emergency response personnel responding to a code if one is called in that area. Therefore, after basic cardiopulmonary resuscitation (airway, breathing, chest compressions) is initiated, the patient should be immediately moved out of Zone IV to a prospectively designated location where the code can be run or where the patient will remain until the arrival of emergent response personnel.

It is strongly advised that all MR facilities perform regular drills to rehearse and refine emergency response protocols to protect patients, MR staff, and responders.

7. Prevention

While it is the nature of emergencies to be surprises, we can anticipate the types of incidents that have higher likelihoods given our facilities, practices, and locations. Every facility can anticipate the potential for flooding, fire, and code situations. In addition to these, many areas (e.g., California and coastal Alaska) can expect earthquakes. The central and southern plains states of the United States can anticipate tornados. Colder climates can expect massive snows or ice storms.

State and federal offices of emergency preparedness are dedicated to anticipating and preparing for the specific threats to your region. These offices can serve as an excellent resource regarding risks and strategies for preparation.

Once a disaster has struck, it is important to assess the immediate needs of the community and to restore those critical patient care services first.

Damage to MRI equipment and facilities may not be repaired as quickly. For gravely incapacitated facilities, semitrailer-based MRI units may be the only means of quickly restoring radiology capacity.

All health care facilities should have emergency preparedness plans. The health care plans for MRI facilities should specifically address the unique aspects of MRI equipment. These plans should define who has the authority to authorize nonemergent quenches, procedures for emergency or backup power for the vacuum pump/cold head, as well as instructions on how to protect gantries and sensitive electronics. Facilities should have the necessary supplies pre-positioned and checklists for preparatory and responsive actions. Emergency preparedness plans should also include information necessary for restoring clinical services, including contacts for MRI system vendor, RF shield vendor, cryogen contractor, MR suite architect and construction contractor, local and state officials, and affiliated hospital and professional organizations.

Below are a few questions that may facilitate the development of an emergency preparedness plan specific to the needs of a facility.

- What are the likely/possible natural disasters to affect the area?
- What are the likely/possible man-made disasters to affect the area?
- Is electrical power likely to be interrupted?
- Would other utilities (natural gas, telecommunications, etc.) likely be interrupted?
- What equipment would be inoperative during the emergency?
- What equipment could be damaged by the emergency?
- What equipment should be provided with critical or backup power?
- If the utility service is not quickly restored, what other risks may arise?
- Would patients and staff be able to get to the facility?
- Would patients or staff be trapped at the facility?
- How critical is each patient care service provided at the facility?
- How does the facility protect the equipment needed to support each service?
- If the facility does not have the resources on site, who can provide them?

ATTACHMENT

C.1.a.MRI Standards and Criteria 7.d.

Revised 2011 (Resolution 19)*

ACR PRACTICE GUIDELINE FOR PERFORMING AND INTERPRETING MAGNETIC RESONANCE IMAGING (MRI)

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Magnetic resonance imaging (MRI) is a multiplanar imaging method based on an interaction between radiofrequency (RF) electromagnetic fields and certain nuclei in the body (usually hydrogen nuclei) after the body has been placed in a strong magnetic field.[1] MRI differentiates between normal and abnormal tissues, providing a sensitive examination to detect disease. This sensitivity is based on the high degree of inherent contrast due to variations in the magnetic relaxation properties of different tissues, both normal and diseased, and the dependence of the MRI signal on these tissue properties.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

A physician must be responsible for all aspects of the study including, but not limited to, reviewing indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating official

[1] See ACR Glossary of MR Terms, 5th edition, 2005.

interpretations (final reports), and assuring the quality of the images and the interpretations.

Physicians assuming these responsibilities for MR imaging of all anatomical areas (exclusive of cardiac MRI) should meet one of the following criteria:

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and involvement with the supervision, interpretation, and reporting of 300 MRI examinations within the last 36 months.[2]

or

Completion of a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include involvement with the supervision, interpretation, and reporting of 500 MRI examinations in the past 36 months.

or

Physicians not board certified in radiology or not trained in a diagnostic radiology residency program who assumes these responsibilities for MR imaging exclusively in a specific anatomical area, excluding cardiac MRI, should meet the following criteria:

Completion of an ACGME approved residency program in the specialty practiced, plus 200 hours of Category 1 CME in MRI to include, but not limited to: MRI physics, recognition of MRI artifacts, safety, instrumentation, and clinical applications of MRI in the subspecialty area where MRI reading occurs; and supervision, interpretation, and reporting of 500 MRI cases in that specialty area in the past 36 months in a supervised situation. For neurologic MRI, at least 50 of the 500 cases must have been MR angiography (MRA) of the central nervous system.

Specific qualifications for physicians performing cardiac MRI are described in the ACR–NASCI–SPR Practice Guideline for the Performance and Interpretation of Cardiac MRI.

Maintenance of Competence

All physicians performing MRI examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily on the basis of continuing experience, a minimum of 100 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this method, continued competency can also be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

Continuing Medical Education

The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME) and should include CME in MRI as is appropriate to the physician's practice needs.

B. Medical Physicist / MR Scientist

The personnel qualified to carry out acceptance testing and monitoring of MRI equipment for the purposes of this guideline include a medical physicist or an MR scientist.

A Qualified Medical Physicist is an individual who is competent to practice independently one or more subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The appropriate subfield of medical physics for this guideline is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

The Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42)

A Qualified MR Scientist is an individual who has a graduate degree in a physical science involving nuclear magnetic resonance (NMR) or MRI. These individuals should have 3 years of documented experience in a clinical MR environment.

The medical physicist/MR scientist must be familiar with the principles of MRI safety for patients, personnel, and the public; the Food and Drug Administration's guidance for MR diagnostic devices; and other regulations pertaining to the performance of the equipment being monitored. The medical physicist/MR scientist must be

[2]Board certification and completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

knowledgeable in the field of nuclear MR physics and familiar with MRI technology, including function, clinical uses, and performance specifications of MRI equipment, as well as calibration processes and limitations of the performance testing hardware, procedures, and algorithms. The medical physicist/MR scientist must have a working understanding of clinical imaging protocols and methods of their optimization. This proficiency must be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

The medical physicist/MR scientist may be assisted in obtaining test data for performance monitoring by other properly trained individuals. These individuals must be properly trained and approved by the medical physicist/MR scientist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The medical physicist/MR scientist must review and approve all measurements. The MR scientist should meet the ACR Practice Guideline for Continuing Medical Education (CME).

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006) [1]

D. Radiology Technologist

The technologist should participate in assuring patient comfort and safety, preparing and positioning the patient for the MRI examination, and obtaining the MRI data in a manner suitable for interpretation by the physician. The technologist should also perform frequent quality control testing in accordance with the MRI manufacturer's recommendations.

The technologist performing MRI should:

1. Be certified by the American Registry of Radiologic Technologists (ARRT), the American Registry of MRI Technologists (ARMRIT), or the Canadian Association of Medical Radiation Technologists (CAMRT) as an MRI technologist (RTMR).

or

2. Be certified by the ARRT and/or have appropriate state licensure and have 6 months supervised clinical experience in MRI scanning.

or

3. Have an associate's degree in an allied health field or a bachelor's degree and certification in another clinical imaging field and have 6 months of supervised clinical MRI scanning.

To assure competence, the responsible physician should evaluate any technologist who began performing MRI prior to October 1996 and who does not meet the above criteria.

Any technologist practicing MRI scanning should be licensed in the jurisdiction in which he/she practices, if state licensure exists. To assure competence, all technologists must be evaluated by the supervising physician.

III. TECHNIQUES AND INDICATIONS

The currently accepted techniques and indications for MRI are discussed in various ACR Practice Guidelines that are based on anatomic sites of examination. It is important that each site offering MRI have documented procedures and technical expertise and appropriate equipment to examine each anatomic site. Because the clinical applications of MRI continue to expand, the enumerated techniques and indications in the reference documents may not be all-inclusive.

Each site's procedures should be reviewed and updated at appropriate intervals. The final judgment regarding appropriateness of a given examination for a particular patient is the responsibility of the ordering physician or other appropriately licensed health care provider and radiologist. The decision to use MRI to scan a particular part of the human body depends on the MRI software and hardware available and the relative cost, efficacy, and availability of alternative imaging methods. The examination should provide images with suitable contrast characteristics, spatial resolution, signal-to-noise ratio, and section geometry appropriate to the specific clinical indications.

IV. POSSIBLE CONTRAINDICATIONS

Possible contraindications include, but are not limited to, the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, certain cochlear implants, and certain other ferromagnetic foreign bodies or electronic devices [2-5]. Possible contraindications should be listed on a screening questionnaire. All patients should be screened for possible contraindications prior to MRI scanning [6-7]. Published test results and/or on-site testing of an identical device or foreign body may be helpful to determine whether a patient with a particular medical device or foreign body may be safely scanned. There is no known adverse effect of MRI on the fetus. The decision to scan during pregnancy should be made on an individual basis [8].

V. SPECIFICATIONS OF THE EXAMINATION

The examination should be performed within parameters currently approved by the FDA. Examinations that use techniques not approved by the FDA may be considered when they are judged to be medically appropriate.

The written or electronic request for an MRI examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

Images should be labeled with the following: a) patient identification, b) facility identification, c) examination date, and d) image orientation indicated by unambiguous polarity symbols (e.g., R, L, A, P, H, F).

VI. DOCUMENTATION

High-quality patient care requires adequate documentation. There should be a permanent record of the MRI examination and its interpretation. Imaging of all appropriate areas, both normal and abnormal, should be recorded in a suitable archival format. If contrast material is administered during the MRI examination, the brand name of the contrast agent and the administered dose should be recorded and included in the permanent record of the MRI examination. An official interpretation (final report) of the MRI findings should be included in the patient's medical record regardless of where the study is performed. Retention of the MRI examination should be consistent both with clinical need and with relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

VII. SAFETY GUIDELINES

Safety guidelines, practices, and policies must be written, enforced, reviewed, and documented at least annually by the supervising physician. These guidelines should take into consideration potential magnetic field interactions for ferromagnetic objects in the MRI environment [9]. They should also consider potential patient hazards (e.g., from magnetic field interactions, tissue heating, and induced electrical currents) and potential hazards posed by implanted objects and materials within the patient as well as other individuals in the MR environment [4-5].

A screening program should be implemented to assure appropriate and safe use of MR contrast material and to reduce the risk of nephrogenic systemic fibrosis (NSF) [10-11]. For further information on ACR screening recommendations see the ACR Manual on Contrast Media [12] and the ACR Guidance Document for Safe MR Practices [8]. Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis.

In pregnancy, gadolinium-based contrast agents (GBCAs) cross the placental barrier, enter the fetal circulation, and pass via the kidneys into the amniotic fluid. Although no definite adverse effects of GBCA administration on the human fetus have been documented, the potential bioeffects of fetal GBCA exposure are not well understood. GBCA administration should therefore be avoided during pregnancy unless no suitable alternative imaging is possible and the benefits of contrast administration outweigh the potential risk to the fetus. (See the ACR–SPR Practice Guideline for the Safe and Optimal Performance of Fetal MRI).

When GBCAs are administered to nursing women, a small amount of the contrast agent is excreted in the breast milk. It is unlikely that the minute amount of GBCA absorbed by a nursing infant's gastrointestinal tract will be harmful. If there is concern on the part of the referring physician, radiologist, or patient, the nursing mother can be advised to discard her breast milk for 24 hours after GBCA administration.

When contrast and/or sedation are necessary, they must be administered in accordance with institutional policy and state and federal law by a qualified practitioner with training in cardiopulmonary resuscitation [13]. (See the ACR–SPR Practice Guideline for the Use of Intravascular Contrast Media and the ACR–SIR Practice Guideline for Sedation/Analgesia.)

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

VIII. EQUIPMENT SPECIFICATIONS

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

IX. QUALITY CONTROL PROGRAM

A documented quality control program must be maintained at the MR site. Quality control testing should be conducted by the technologist and/or service engineer with review at least annually by the supervising physician and/or a medical physicist/MR scientist [14-16].

X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web site (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web site (http://www.acr.org/guidelines) by the ACR Commission on Body Imaging.

Principal Reviewer:
Jeffrey J. Brown, MD, MBA, FACR

Commission on Body Imaging – ACR Committee responsible for sponsoring the draft through the process

James A. Brink, MD, FACR, Chair
Lincoln L. Berland, MD, FACR
Steven E. Harms, MD, FACR
Ella A. Kazerooni, MD, FACR
Mark J. Kransdorf, MD, FACR
Joel F. Platt, MD
Geoffrey D. Rubin, MD
Bill H. Warren, MD, FACR
Judy Yee, MD

Comments Reconciliation Committee
Rodney S. Owen, MD, FACR, Chair
Kimberly E. Applegate, MD, MS, FACR
James A. Brink, MD, FACR
Jeffrey J. Brown, MD, MBA, FACR
Philip N. Cascade, MD, FACR
Howard B. Fleishon, MD, MMM, FACR
Allan J. Fox, MD
Alan D. Kaye, MD, FACR
Paul A. Larson, MD, FACR

REFERENCES

1. ACR ASRT joint statement. Radiologist assistant roles and responsibilities. *Digest of Council Actions*. Reston, Va: American College of Radiology; 2008:147.
2. Kanal E, Shellock FG. Aneurysm clips: effects of long-term and multiple exposures to a 1.5-T MR system. *Radiology* 1999;210:563-565.
3. Kanal E, Shellock FG, Lewin JS. Aneurysm clip testing for ferromagnetic properties: clip variability issues. *Radiology* 1996;200:576-578.
4. Shellock FG. *Magnetic Resonance Procedures: Health Effects and Safety*. Boca Raton, Fla: CRC Press; 2000.
5. Shellock FG. *The Reference Manual for Magnetic Resonance Safety. Implants and Devices 2010*. Los Angeles, Calif: Biomedical Research Publishing Company; 2010.
6. Elster AD, Link KM, Carr JJ. Patient screening prior to MR imaging: a practical approach synthesized from protocols at 15 U. S. medical centers. *AJR* 1994;162:195-199.
7. Sawyer-Glover AM, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices. *J Magn Reson Imaging* 2000;12:510.

8. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document for safe MR practices: 2007. *AJR* 2007;188:1447-1474.
9. Hartwig V, Giovannetti G, Vanello N, Lombardi M, Landini L, Simi S. Biological effects and safety in magnetic resonance imaging: a review. *Int J Environ Res Public Health* 2009;6:1778-1798.
10. Weinreb JC, Kuo PH. Nephrogenic systemic fibrosis. *Magn Reson Imaging Clin N Am* 2009;17:159-167.
11. Kuo PH. Gadolinium-containing MRI contrast agents: important variations on a theme for NSF. *J Am Coll Radiol* 2008;5:29-35.
12. American College of Radiology. Manual on Contrast Media, Version 7; 2010. http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx. (accessed July 12, 2010)
13. Cutter TW. Radiologists and anesthesiologists. *Anesthesiol Clin* 2009;27:95-106.
14. Bourel P, Gibon D, Coste E, Daanen V, Rousseau J. Automatic quality assessment protocol for MRI equipment. *Med Phys* 1999;26:2693-2700.
15. Price RR, Axel L, Morgan T, et al. Quality assurance methods and phantoms for magnetic resonance imaging: report of AAPM nuclear magnetic resonance Task Group No. 1. *Med Phys* 1990;17:287-295.
16. Wood ML, Price RR. Quality control problems for MRI. In: Sprawls P, Bronskill M, ed. *The Physics of MRI: AAPM summer school proceedings 1992*. New York, NY: American Institute of Physics; 1992:718-753.

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
1992 (Resolution 14)
Amended 1995 (Resolution 53)
Revised 1996 (Resolution 1)
Revised 2000 (Resolution 16)
Revised 2001 (Resolution 12)
Amended 2002 (Resolution 2)
Revised 2006 (Resolution 15,16g,34,35,36)
Revised 2011 (Resolution 19)

ATTACHMENT

C.1.a.MRI Standards and Criteria 7.g.

The Hospitalist Company

ipc

March 7, 2013

To Whom It May Concern:

This is notification that the physicians of IPC of Tennessee provide hospital admissions and inpatient care for patients of **Medical Care, PLLC, 1500 W. Elk Avenue, Elizabethton, TN 37643**

IPC of Tennessee physicians are available to admit patients at the following facilities, 7 days per week, 24 hours per day. The IPC of Tennessee physician on call can be reached at the numbers listed below.

Johnson City Medical Center, Johnson City, TN	(423) 854-2222	Franklin Transitional Care, Johnson City, TN	(888) 877-6975
Holston Valley Medical Center, Kingsport, TN	(888) 601-6073	Health South Rehabilitation Hospital, Kingsport, TN	(423) 246-7240
Sycamore Shoals Hospital, Elizabethton, TN	(423) 410-1955	Quillen Rehabilitation Hospital, Johnson City, TN	(423) 952-1700
Bristol Regional Medical Center, Bristol, TN	(888) 214-9443	Health South Rehabilitation Hospital, Bristol, VA	(276) 642-7908

Following is a list of physicians on staff at IPC of TN.

Last Name	First Name	NPI	Last Name	First Name	NPI
Abu-Zeitoon MD	Rawan	1265621072	Mahboob, MD	Rashid	1659356335
Adams, DO	Stephanie A.	1023289493	Mann, MD	John	1104811694
Aimua, MD	Benedict E.	1962674424	Martin, MD	Jei	1033104047
Ali, MD	Muhammad	1265626279	Meade, DO	Farida E.	1174717235
Belagode, MD	Vinaya S	1518048172	Nazarov, MD	Vitaly	1760469084
Clark MD	Vivian	1205889508	Obuekwe, MD	Uzoma	1992901409
Collnger MD	J.W	1245283886	Ozuah, MD	Uchenna	1578883377
Colinger DO	Jason	1609829241	Paris, MD	Claire	1063465128
Daniel DO	John	1013987023	Pickstock, MD	Janet G.	1215914528
Diaz Valdes, MD	Sergio A.	1417138439	Porter, MD	Keith G.	1821036179
Donovan, MD	Brian P	1598741787	Quinn, MD	Donald R.	1447219688
Garrido, MD	Jose A.	1982640140	Sawaf, DO	John N.	1346347358
Gonce, MD	Joel	1114920188	Singh, MD	Parminderjit	1396903126
Gutta, MD	Veerendra	1457362162	Squires MD	Anne Charlotte	1871586917
Holt, MD	Jacob E.	1194831636	Starr, MD	Dennis	1477727816
Jackson, MD	Richard	1457359770	Theerathorn, MD	Pitchar	1548223084
Jastan, MD	Rasmiyah	1740474527	Tountcheva, MD	Dimka M.	1316924665
Jurdi, MD	Makram	1124281894	Udoeyop, MD	U. Walter	1730166083
Kharalkar, MD	Shweta	1851585996	Vashsit MD	Amit	1598950644
Kopparapu MD	Anil	1487891401	Walker, MD	Robert W	1902877137
Lamb MD	Ray	1497858575			

If you have any questions, please contact Sharon Alvis at (423) 282-1480 extension 314.

Sincerely,

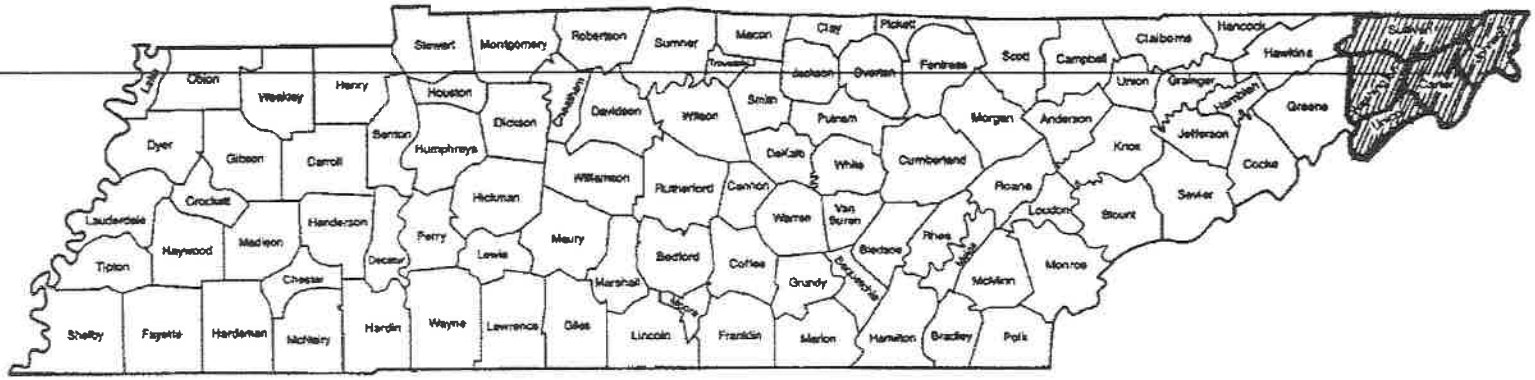
Louis Collier

Louis Collier, Director of Operations, TN Region

ATTACHMENT C.3.

Medical Care, PLLC

Proposed MRI Service area



Proposed service area includes; Carter, Johnson, Unicoi, Sullivan, and Washington counties in Tennessee

ATTACHMENT C

Economic Feasibility 1

DESIGN BUILD CONSTRUCTION, LLC

March 8, 2012

Steve Hopland, CEO
Medical Care, LLC
1500 West Elk Avenue
Elizabethton, TN 37643

RE: MRI Renovation Project, Medical Care, LLC, 1500 West Elk Avenue, Elizabethton, TN 37643

Dear Steve:

As your design architect and design build contractor you have asked that we assist in preparation of your needed documentation for the above referenced MRI renovation project. As we understand the scope of work, you will be contracting with National MRI Shielding to provide the design and actual MRI equipment and installation of including auxiliary equipment and required shielding for the project. Facility improvements that would be required include the following:

- HVAC needs to condition the space
- Electrical material and labor to energize MRI equipment, HVAC equipment and new nonmetallic lights
- Gypsum board walls to add a mechanical room and to cover up new shielding metal
- Paint
- Demolition required to get MRI through exterior walls and into the proposed room space and repair back
- Additional flooring and base
- Reworked sprinkler head locations

You will find a budget estimate of that scope attached. We expect that your selected contractor for MRI installation has covered the design and cost to handle any influence of the magnetic field in relationship to the activities of the occupants adjacent to the proposed area. Per the preliminary electrical power needs you have shared with the electrical subcontractor he has stated that the electrical system has adequate capacity to support sufficient power to the magnet.

To the best of my knowledge at this time we have considered all applicable federal, state and local construction codes, standards, specifications, and known requirements and we feel the renovated facility will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the 2006 AIA Guidelines for Design and Construction of Hospital and Health Care Facilities and Department of Health Rules pertaining to Outpatient Diagnostic Centers.

We thank you for the opportunity to be of service. Please call us if you have further needs or questions.

Sincerely,

Roger Barnett

Roger Barnett, AIA
President / Owner

CC: Brian Briscall, John Crewey

354 Shadowtown Road, Suite 200 Blountville, TN 37617 423-279-0540 Fax 423-279-0541 www.dbconstllc.com

Project name	MRI Room 1500 West Elk Avenue Elizabethton TN 37643
Estimator	R. Barnett
Labor rate table	Standard Labor
Equipment rate table	Standard Equipment
Job size	576 SF
Bid date	3/6/2013 4:00 PM
Report format	Sorted by 'Group phase/Phase' 'Detail' summary

Item	Description	Takeoff Qty		Total Amount
1000.000	***GENERAL REQUIREMENTS***			
1210.020	**Engineer/Architect Fees**			
12	Architect Fee			1,000
	Engineer/Architect Fees			**1,000**
1300.010	**Personnel: Supervision**			
10	Superintendent	3.00	wk	2,460
	Personnel: Supervision			**2,460**
	120.00 Labor hours			
	120.00 Equipment hours			
1310.010	**Personnel: Proj. Managmnt**			
70	Estimator	0.10	mo	360
80	Purchasing Agent	0.10	mo	360
100	Payroll Clerk	0.30	wk	180
	Personnel: Proj. Managmnt			**900**
	12.00 Labor hours			
1310.020	**Travel: All Types**			
40	Car Travel			100
	Travel: All Types			**100**
1510.010	**Utilities: Temporary**			
10	Temp Electricity (by landlord)	1.00	mo	1
15	Temporary Lighting	1.00	ea	50
40	Temp Phone	1.00	mo	35
60	Temp Water (by landlord)	1.00	mo	1
	Utilities: Temporary			**87**
1520.020	**Temp: Supplies**			
40	Blue Prints	10.00	ea	24
	Temp: Supplies			**24**
1540.010	**Temp: Tools & Equipment**			
10	Tools & Equipment	1.00	mo	158
50	Oil & Gas	1.00	mo	100
	Temp: Tools & Equipment			**258**
	13.533 Labor hours			
1562.010	**Controls: Safety**			
30	First Aid Equip	1.00	mo	30
40	Safety Meetings	3.00	wk	30
	Controls: Safety			**60**
	1.20 Labor hours			
	GENERAL REQUIREMENTS			***4,889***
	146.733 Labor hours			
	120.00 Equipment hours			
1730.000	***DEMOLITION***			
1734.010	**Demo: Masonry**			
40	Saw Masonry	24.00	lf	50
60	Rem Brick For Opening (Hand)	20.00	sf	96
70	Rem Block For Opening (Hand)	20.00	sf	96

Item		Description	Takeoff Qty		Total Amount
		Demo: Masonry			**242**
		10.40 Labor hours			
		2.00 Equipment hours			
1736.010		**Demo: Wood**			
	30	Remove Studs & Finish	216.00	sf	713
		Demo: Wood			**713**
		21.60 Labor hours			
		10.80 Equipment hours			
1738.010		**Demo: Doors & Windows**			
	40	Remove Door & Frame	1.00	ea	15
	70	Remove Aluminum Storefront Door & Frame & Reuse	1.00	ea	30
		Demo: Doors & Windows			**45**
		3.00 Labor hours			
1739.090		**Demo: Exterior Finishes**			
	30	Remove Stucco (Dryvit)	40.00	sf	44
		Demo: Exterior Finishes			**44**
		2.00 Labor hours			
		0.40 Equipment hours			
1740.010		**Clean Up**			
	10	Current Cleanup	3.00	wk	630
		Clean Up			**630**
		30.00 Labor hours			
1780.010		**Punchlist, Etc**			
	10	Punchlist, etc	1.00	ea	200
		Punchlist, Etc			**200**
		10.00 Labor hours			
		DEMOLITION			***1,875***
		77.00 Labor hours			
		13.20 Equipment hours			
6000.000		***WOOD & PLASTICS***			
6110.010		**Framing: Plates**			
	16	Plates 2x4x16	4.00	ea	47
		Framing: Plates			**47**
		1.681 Labor hours			
6110.020		**Framing: Plates PT**			
	16	Plates PT 2x4x16	2.00	ea	23
		Framing: Plates PT			**23**
		0.840 Labor hours			
6112.010		**Framing: Studs 2x4 > 2x8**			
	30	Studs 2x4x10	15.00	ea	110
	40	Studs 2x4x12	18.00	ea	158
		Framing: Studs 2x4 > 2x8			**268**
		9.76 Labor hours			
		WOOD & PLASTICS			***338***
		12.281 Labor hours			

Item	Description	Takeoff Qty		Total Amount
7000.000	***THERMAL & MOISTURE PROT***			
7240.010	**Ext Insulation/Finish Sys**			
30	Primus/Adhesive	40.00	sf	27
60	Reinforcing Mesh: Hi Impact	40.00	sf	17
90	Sandblast Finish Coat	40.00	sf	25
	Ext Insulation/Finish Sys			**69**
	3.00 Labor hours			
	THERMAL & MOISTURE PROT			***69***
	3.00 Labor hours			
8000.000	***DOORS & WINDOWS***			
8210.010	**Doors: Wood**			
bh 6	6 Panel Masonite HB Core 3-0 x 6-8 w/ Flat jambs & trim	2.00	ea	792
	Doors: Wood			**792**
	8.00 Labor hours			
8400.000	**Metal-Framed Storefronts**			
10	Aluminum-Framed Storefront Remove & Reinstall	80.00	sf	1,500
	Metal-Framed Storefronts			**1,500**
8700.000	**Hardware: Finishing**			
40	Wall Stops	2.00	ea	18
60	Rubber Silencer	6.00	ea	13
180	Lever Lockset	2.00	ea	259
	Hardware: Finishing			**289**
	4.80 Labor hours			
	DOORS & WINDOWS			***2,581***
	12.80 Labor hours			
9000.000	***FINISHES***			
9131.010	**GWB: Boards & Sheathing**			
230	GWB 5/8x12 Fire Code	840.00	sf	373
	GWB: Boards & Sheathing			**373**
9132.010	**GWB: Finish Mud/Tape**			
10	Labor GWB Finish All Steps	840.00	sf	158
30	Joint Compound	840.00	sf	13
40	Joint Tape 500' Rolls	840.00	sf	5
	GWB: Finish Mud/Tape			**176**
	10.50 Labor hours			
9511.010	**Ceiling: Grid Mains**			
50	Hanger Wire (#12 ga.)	200.00	lf	9
120	Main Tee Intermediate White	100.00	lf	54
	Ceiling: Grid Mains			**63**
	2.00 Labor hours			
9511.030	**Ceiling: 2' Tee**			
20	Cross Tee 2' Aluminum Solid	20.00	ea	53

Item		Description	Takeoff Qty		Total Amount
		Ceiling: 2' Tee			53
		1.00 Labor hours			
9511.040		**Ceiling: Wall Mold**			
	20	Wall Mold 15/16 Angle White	60.00	lf	27
		Ceiling: Wall Mold			**27**
		1.20 Labor hours			
9511.050		**Ceiling: 2x4 Tile**			
	120	MinFbr SqEdge Std 2x4 3/4"	120.00	sf	91
		Ceiling: 2x4 Tile			**91**
		1.25 Labor hours			
9650.010		**Flooring Resilient**			
	10	Floor Resil Vinyl Tile @ added space	144.00	sf	341
	20	Floor Resil Base @ added space	60.00	lf	63
		Flooring Resilient			**404**
		6.120 Labor hours			
9910.020		**Painting: Int Detailed**			
	5	Paint Interior Complete	1,000.00	ls	1,600
		Painting: Int Detailed			**1,600**
		100.00 Labor hours			
		FINISHES			***2,787***
		122.070 Labor hours			
15000.000		***MECHANICAL***			
15300.010		**Sprinkler**			
	10	Fire Protection (Lump Sum)			1,200
		Sprinkler			**1,200**
15700.000		**HVAC Systems**			
	10	HVAC Systems (Lump Sum)			18,000
		HVAC Systems			**18,000**
		MECHANICAL			***19,200***
16000.000		***ELECTRICAL***			
16000.010		**Electrical Complete**			
	10	Electrical (Lump Sum)			15,000
		Electrical Complete			**15,000**
		ELECTRICAL			***15,000***

Estimate Totals

Description	Amount	Totals	Hours	Rate		Cost Basis	ıt per Unit	·ent of Total	
Labor	5,527		373.884 hrs				9.596 /SF	10.26%	
Labor Burden	2,764			50.000 %		C	4.798 /SF	5.13%	
	8,291	8,291					14.394 /SF	15.38	15.38%
Liability Insurance	251			30.250 $ /	1.000	T	0.435 /SF	0.47%	
	251	8,542					14.830 /SF	0.47	15.85%
Material	2,458						4.267 /SF	4.56%	
Tenn Sales Tax	240			9.750 %		C	0.416 /SF	0.44%	
	2,698	11,240					19.514 /SF	5.01	20.86%
Subcontract	37,310						64.774 /SF	69.23%	
Equipment	580		133.200 hrs				1.007 /SF	1.08%	
ilding Permit Etc.	400					L	0.694 /SF	0.74%	
Other	862						1.497 /SF	1.60%	
	39,152	50,392					87.486 /SF	72.64	93.50%
ead & Profit Fees	3,503			6.500 %		T	6.082 /SF	6.50%	
	3,503	53,895					93.568 /SF	6.50	100.00%
Total		***53,895***					***93.568 /SF***		

ATTACHMENT C

Economic Feasibility 2.A.

P.O. Box 940
Johnson City, TN 37605-0940

State of Franklin BANK
A division of Jefferson Federal Bank

P.O. Box 208
Kingsport, TN 37662-0208

January 4, 2013

Mr. Steve Hopland
Medical Care PLLC
1500 West Elk Avenue
Elizabethton, TN 37643

Dear Mr. Hopland:

State of Franklin Bank, a division of Jefferson Federal Bank, is pleased to offer you the following proposals to finance the purchase of a G.E. 1.5T MRI, as further described in Contract of Sale #092212A from M.E.D. Inc and a GE Signa 1.5T Excite 8-Channel MRI described in Agreement Number 121712-WH from Oxford Instruments, along with related attachments/expenses associated with the installation. The proposal is subject to the satisfactory review of all financial information on the borrower(s) and conditions to meet the bank's lending policy and/or state and federal guidelines and should not be construed to be final approval.

Loan Amount:	$675,000
Interest Rate:	5.00%
Amortization:	For a period not to exceed 60 months.
Origination Fee:	None.
Repayment Terms:	The fixed monthly principal and interest payments based on an amortization period not to exceed 60 months.
Loan to Value:	N/A
Collateral:	Equipment to be purchased along with all attachments.
Guarantors:	Dr. Arnold Hopland, Dr. Jeffery Hopland, Dr. Kenneth Hopland, Steve Hopland and Jennifer Whaley, along with all spouses.
Environmental Assessment:	N/A
Insurance:	A mortgage policy naming State of Franklin Bank, a division of Jefferson Federal Bank, as mortgagee shall be required at closing.

Closing Cost:	The borrower shall be responsible for all closing costs associated with this loan including but not limited to attorney fees, appraisal fees, environmental assessments or any other cost. If the loan does not close, any fees generated will be paid by the borrower upon request by the bank.
Prepayment:	No prepayment fee will be assessed.
Other terms & Conditions:	A Balance Sheet and Income Statement, along with prior year tax returns, shall be delivered to the bank on a timely basis after the fiscal year on all borrowers or anytime the bank deems necessary.

The Directors, Officers and staff are pleased you have given the bank the opportunity to finance your request. If you have any questions please feel free to call.

Sincerely,

Harvey L. Mitchell
President, Tri-Cities Division

Acceptance of these terms and conditions are required by February 15, 2013 and closed by March 15, 2013. Any changes to these terms and condition shall be in writing and approved by State of Franklin Bank.

Accepted:

BY_____ _____ _____

Title Date

ATTACHMENT C

Economic Feasibility 4

PROJECT COSTS CHART

2013 MAR 13 AM 9 58

A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	3,500
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	15,000
3.	Acquisition of Site	0
4.	Preparation of Site	5,000
5.	Construction Costs	80,220
6.	Contingency Fund	50,000
7.	Fixed Equipment (Not included in Construction Contract)	426,984
8.	Moveable Equipment (List all equipment over $50,000)	18,000
9.	Other (Specify)	
B.	Acquisition by gift, donation, or lease:	
1.	Facility (inclusive of building and land) 5 year lease	117,950
2.	Building only	
3.	Land only	
4.	Equipment (Specify)	
5.	Other (Specify)	
C.	Financing Costs and Fees:	
1.	Interim Financing	
2.	Underwriting Costs	
3.	Reserve for One Year's Debt Service	118,889
4.	Other (Specify)	
D.	Estimated Project Cost (A+B+C)	835,543
E.	CON Filing Fee	3,000
F.	Total Estimated Project Cost (D+E)	838,543
	TOTAL	838,543

2013 MAR 13 AM 10 00

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in [January] (Month).

	Year [2010]	Year [2011]	Year [2012]
A. Utilization Data (Specify unit of measure) CPT's	233,492	260,351	254,696
B. Revenue from Services to Patients			
1. Inpatient Services	$ -	$ -	$ -
2. Outpatient Services	$15,349,854	$17,411,255	$18,228,256
3. Emergency Services	-	-	-
4. Other Operating Revenue (Specify)	-	-	-
Gross Operating Revenue	$ 15,349,854	$ 17,411,255	$ 18,228,256
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	$ 6,769,519	$ 7,612,200	$ 8,403,226
2. Provision for Charity Care	920,991	748,684	747,358
3. Provisions for Bad Debt	461,927	554,347	1,044,229
Total Deductions	$ 8,152,437	$ 8,915,231	$ 10,194,813
NET OPERATING REVENUE	$ 7,197,417	$ 8,496,024	$ 8,033,443
D. Operating Expenses			
1. Salaries and Wages	$ 1,875,470	$ 2,155,904	$ 2,290,216
2. Physician's Salaries and Wages	2,080,586	2,054,709	2,106,806
3. Supplies	174,800	213,389	260,316
4. Taxes	303,499	354,482	249,982
5. Depreciation	376,472	384,042	195,462
6. Rent			
7. Interest, other than Capital			
8. Other Expenses (Specify) [Management]	2,357,923	2,393,264	2,624,563
Total Operating Expenses	$ 7,168,750	$ 7,555,790	$ 7,727,345
E. Other Revenue (Expenses) – Net (Specify)	$	$	$
NET OPERATING INCOME (LOSS)	$ 28,667	$ 940,234	$ 306,098
F. Capital Expenditures			
1. Retirement of Principal	$ (1,462,695)	$ (506,331)	$ (4,404,830)
2. Interest	149,922	247,016	351,847
Total Capital Expenditures	$ (1,312,773)	$ (259,315)	$ (4,052,983)
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	$ 1,341,440	$ 1,199,549	$ 4,359,081

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in [January] (Month).

		Year [1]	Year [2]
A.	Utilization Data (Specify unit of measure)	2756	2894
B.	Revenue from Services to Patients		
	1. Inpatient Services	$	$
	2. Outpatient Services	4,369,775.80	4,588,581.70
	3. Emergency Services		
	4. Other Operating Revenue (Specify)		
	Gross Operating Revenue	$ 4,369,776	$ 4,588,581
C.	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$ 1,909,591	$ 2,005,210
	2. Provision for Charity Care	218,489	229,429
	3. Provisions for Bad Debt	131,093	137,657
	Total Deductions	$ 2,259,173	$ 2,372,296
NET OPERATING REVENUE		$ 2,110,603	$ 2,216,285
D.	Operating Expenses		
	1. Salaries and Wages	$ 282,800	$ 318,500
	2. Physician's Salaries and Wages	206,700	217,050
	3. Supplies	275,600	289,400
	4. Taxes		
	5. Depreciation	75,000	75,000
	6. Rent	23,590	23,590
	7. Interest, other than Capital		
	8. Other Expenses (Specify) [Service / Marketing]	150,000	150,000
	Total Operating Expenses	$ 1,013,690	$ 1,073,540
E.	Other Revenue (Expenses) -- Net (Specify)	$	$
NET OPERATING INCOME (LOSS)		$ 1,096,913	$ 1,142,745
F.	Capital Expenditures		
	1. Retirement of Principal	$ 94,792	$ 99,641
	2. Interest	24,097	19,248
	Total Capital Expenditures	$ 118,889	$ 118,889
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$ 978,024	$ 1,023,856

ATTACHMENT C

Economic Feasibility 10

RHP
Certified Public Accountants

November 8, 2012

To the Members
Pine Palms Management, LLC
Johnson City, Tennessee

We have compiled the accompanying statements of assets, liabilities, and equity – income tax basis of Pine Palms Management, LLC, as of September 30, 2012 and the related statement of revenues, expenses and members' equity – income tax basis for the nine months then ended. We have not audited or reviewed the accompanying financial statements and, accordingly, do not express an opinion or provide any assurance about whether the financial statements are in accordance with the income tax basis of accounting.

Management is responsible for the preparation and fair presentation of the financial statements in accordance with the income tax basis of accounting and for designing, implementing and maintaining internal control relevant to the preparation and fair presentation of the financial statements.

Our responsibility is to conduct the compilation in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. The objective of a compilation is to assist management in presenting financial information in the form of financial statements without undertaking to obtain or provide any assurance that there are no material modifications that should be made to the financial statements.

Management has elected to omit substantially all of the disclosures ordinarily included in financial statements prepared in accordance with the income tax basis of accounting. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Corporation's assets, liabilities, equity, revenues and expenses. Accordingly, these financial statements are not designed for those who are not informed about such matters.

Richard H Perry, CPA, PC

620 Mabry Hood Rd . Suite 201. Knoxville, TN 37932
p 865.392.4010 | f 865.670.7565 | www.rhptn.com

PINE PALMS MANGEMENT, LLC and MEDICAL CARE, PLLC

COMBINED STATEMENT OF REVENUE, EXPENSES AND EQUITY - INCOME TAX BASIS

For the nine months ended September 30, 2012

	09/30/12	
FEES - net of refunds	$ 5,962,279.25	100.00%
EXPENSES		
Salaries and wages - others	2,434,299.85	40.83%
Advertising	8,079.90	0.14%
Bank charges	9,000.82	0.15%
Business gifts and entertainment	7,280.15	0.12%
Continuing Education	7,719.34	0.13%
Employee benefits	183,910.65	3.08%
Insurance expense	77,862.54	1.31%
Interest expense	108,486.71	1.82%
Licenses and permit	6,718.03	0.11%
Medical and laboratory supplies	1,104,617.55	18.53%
Office supplies and postage	115,080.51	1.93%
Outside Services	172,264.24	2.89%
Payroll taxes	203,565.43	3.41%
Professional fees	121,919.58	2.04%
Provision for depreciation	195,462.46	3.28%
Retirement contributions	20,114.68	0.34%
Repairs and maintenance	109,048.79	1.83%
Taxes and licenses	28,632.38	0.48%
Travel	8,271.25	0.14%
Utilities, telephone and elevator	140,522.70	2.36%
	5,062,857.56	84.91%
NET OPERATING INCOME BEFORE MEMBERS' COMPENSATION	899,421.69	15.09%
MEMBERS' COMPENSATION		
Guaranteed payments-members	565,409.51	9.48%
	565,409.51	9.48%
NET OPERATING INCOME	334,012.18	5.60%
OTHER INCOME	71,686.84	1.20%
TOTAL OPERATING INCOME	405,699.02	6.80%
Members' equity at January 1, 2012	386,255.07	
Members' withdrawals	(375,000.00)	
MEMBERS' EQUITY AT SEPTEMBER 30, 2012	$ 416,954.09	

See accountants' compilation report.

PINE PALMS MANAGEMENT, LLC and MEDICAL CARE, PLLC

COMBINED STATEMENT OF ASSETS, LIABILITIES AND EQUITY - INCOME TAX BASIS

September 30, 2012

ASSETS

CURRENT ASSETS		
Cash		$ 372,278.86
Due from employees		2,754.15
Due from officers		98,492.24
	TOTAL CURRENT ASSETS	473,525.25
PROPERTY AND EQUIPMENT - at cost		
Land		296,278.72
Buildings and Construction in Progress		8,571,294.12
Furniture, fixtures & equipment		1,934,708.89
Software		45,137.62
		10,847,419.35
Less accumulated depreciation		2,694,547.32
		8,152,872.03
OTHER ASSETS		
Due from Medical Software Solutions, LLC		48,500.00
Note receivable- Dr. Church		99,841.62
		148,341.62
	TOTAL ASSETS	$ 8,774,738.90

LIABILITIES

CURRENT LIABILITIES		
Payroll taxes payables		607.94
Loan from officer		$ 200,000.00
Current portion of long term debt		178,005.21
	TOTAL CURRENT LIABILITIES	378,613.15
LONG TERM DEBT, net of current portion		7,979,171.66
	TOTAL LIABILITIES	8,357,784.81
MEMBERS' EQUITY		416,954.09
	TOTAL LIABILITIES AND MEMBERS' EQUITY	$ 8,774,738.90

PINE PALMS MANGEMENT, LLC and MEDICAL CARE, PLLC

COMBINED STATEMENT OF CASH FLOW - INCOME TAX BASIS

For the nine months ended September 30, 2012

CASH FLOWS FROM OPERATING ACTIVITIES		
Net income from operations	$	405,699.02
Decrease in receivables from employees and others		135.22
Decrease in payroll liabilites		(15,842.97)
NET CASH PROVIDED BY OPERATING ACTIVITIES		389,991.27
CASH FLOWS FROM INVESTING ACTIVITIES		
Increase in Buildings, Furniture and Equipment		(4,124,759.01)
Increase in accumulated depreciation		195,462.46
Decrease in Note Receivable from Dr. Church		6,694.89
NET CASH USED BY INVESTING ACTIVITIES		(3,922,601.66)
CASH FLOWS FROM FINANCING ACTIVITIES		
Increase in notes payable		4,279,721.00
Distributions to members		(375,000.00)
NET CASH PROVIDED BY FINANCING ACTIVITIES		3,904,721.00
INCREASE IN CASH		372,110.61
CASH AT BEGINNING OF PERIOD		168.25
CASH AT SEPTEMBER 30, 2012	$	372,278.86

See accountants' compilation report.

PROOF OF PUBLICATION

STATE OF TENNESSEE
COUNTY OF CARTER

Judy C. Guinn OF SAID COUNTY BEING DULY SWORN, DEPOSETH AND SAITH THAT SHE IS THE ASSISTANT TREASURER OF THE ELIZABETHTON STAR, A NEWSPAPER PUBLISHED AT ELIZABETHTON IN THE COUNTY OF CARTER, STATE OF TENNESSEE, AND THE ORDER AND NOTICE, OF WHICH IS ANNEXED IS A TRUE COPY, WHICH WAS PUBLISHED IN SAID PAPER FOR One-Day ~~CONSECUTIVE WEEKS,~~

~~COMMENCING ON~~ THE 8th DAY OF Mar., 2013
~~AND ENDING~~ ON THE 8th DAY OF Mar., 2013

Sworn to and subscribed before me this
the 8th day of Mar., 2013

Judy C. Guinn

Nathan C. Goodwin

NOTARY PUBLIC

My commission expires *November 19, 2014*

NATHAN C. GOODWIN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF CARTER

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 66-1601 *et seq.*, and the Rules of the Health Services and Development Agency that Medical Care, PLLC, professional private practice, owned by: Medical Care, PLLC with an ownership type of professional limited liability company and to be managed by: Pine Palms Management, LLC intends to file an application for a Certificate of Need for initiation of magnetic resonance imaging (MRI) services to its patients at 1500 West Elk Avenue in Elizabethton, Carter County, Tennessee. The project costs are $838,543. The project does not include the acquisition of major medical equipment, will not require facility licensure and affects no licensed inpatient bed complements.

The anticipated date of filing the application is: March 8, 2013. The contact person for this project is Rachel C. Nelley, Esq., Attorney, who may be reached at Nelley & Company, PLLC, P.O. Box 150731, Nashville, TN 37215, (615) 274-4839.

Upon written request by interested parties, a local Fact-Finding hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled: and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Development Agency
Certificate-of-Need
Published: March 8, 2013
Cost: $204.00

Project Completion Forecast Chart

PROJECT COMPLETION FORECAST CHART

2013 MAR 13 AM 10 01

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68-11-1609(c): June 26,2013

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed	7	July / 2013
2. Construction documents approved by the Tennessee Department of Health	N/A	
3. Construction contract signed	7	July / 2013
4. Building permit secured	14	July / 2013
5. Site preparation completed	14	Aug / 2013
6. Building construction commenced	7	Aug / 2013
7. Construction 40% complete	30	Sept / 2013
8. Construction 80% complete	30	Oct / 2013
9. Construction 100% complete (approved for occupancy	14	Nov / 2013
10. *Issuance of license	N/A	
11. *Initiation of service	7	Nov / 2013
12. Final Architectural Certification of Payment	14	Nov / 2013
13. Final Project Report Form (HF0055)	14	Dec / 2013

* **For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

2013 MAR 13 AM 10 01

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Carter

Arnold O Hopland, MD, being first duly sworn, says that he/she is the applicant named in this application or his/her lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Tennessee Health Services and Development Agency and T.C.A. § 68-11-1601, *et seq.*, and that the responses to questions in this application or any other questions deemed appropriate by the Tennessee Health Services and Development Agency are true and complete.

MD

Signature/Title

Sworn to and subscribed before me this the 7 day of March, 2013, a Notary Public in and for the County of Carter State of Tennessee.

NOTARY PUBLIC

My Commission expires Aug 2, 2014

CAROL O'BOURKE STATE OF TENNESSEE NOTARY PUBLIC CARTER COUNTY

HF-0056
Revised 7/02 - All forms prior to this date are obsolete

State of Tennessee
Health Services and Development Agency
Frost Building, 3rd Floor, 161 Rosa L. Parks Boulevard, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

May 1, 2013

Rachel C. Nelley, Esq.
Nelley & Company, PLLC
PO Box 150731
Nashville, TN 37215

RE: Certificate of Need Application -- Medical Care, PLLC - CN1303-006

Dear Ms. Nelley:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need for the initiation of magnetic resonance imaging (MRI) services for the patients of Medical Care, PLLC and acquisition of a MRI unit at 1500 West Elk Avenue, Elizabethton (Carter County), Tennessee 37643. The proposed service area consists of Carter, Johnson, Sullivan, Unicoi and Washington counties. Estimated Project Cost is $838,543.00.

Please be advised that your application is now considered to be complete by this office. Your application is being forwarded to the Tennessee Department of Health and/or its representative for review.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on May 1, 2013. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on July 24, 2013.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill
Executive Director

MMH:MAB

cc: Dan Henderson, Director, Division of Health Statistics

State of Tennessee
Health Services and Development Agency
Frost Building, 3rd Floor, 161 Rosa L. Parks Boulevard, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

MEMORANDUM

TO: Dan Henderson, Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, Tennessee 37247

FROM: Melanie M. Hill
Executive Director

DATE: May 1, 2013

RE: Certificate of Need Application
Medical Care, PLLC - CN1303-006

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on May 1, 2013 and end on July 1, 2013.

Should there be any questions regarding this application or the review cycle, please contact this office.

MMH:MAB

Enclosure

cc: Rachel C. Nelley, Esq.

2013 MAR 8 AM 10 01

LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Elizabethton Star (Name of Newspaper) which is a newspaper of general circulation in Carter (County), Tennessee, on or before March 8 (Month / day), 2013 (Year) for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency,

Medical Care, PLLC (Name of Applicant) professional private practice (Facility Type-Existing)

owned by: Medical Care, PLLC with an ownership type of professional limited liability company and to be managed by: Pine Palms Management, LLC intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]:

initiation of magnetic resonance imaging (MRI) services to its patients at 1500 West Elk Avenue in Elizabethton, Carter County, Tennessee. The project costs are $838,543. The project does not include the acquisition of major medical equipment, will not require facility licensure and affects no licensed inpatient bed complements.

The anticipated date of filing the application is: March 13, 2013

The contact person for this project is Rachel C. Nelley, Esq. (Contact Name) Attorney (Title)

who may be reached at: Nelley & Company, PLLC (Company Name) PO Box 150731 (Address)

Nashville (City) TN (State) 37215 (Zip Code) (615) 274-4838 (Area Code / Phone Number)

Rachel C. Nelley (Signature) 03-06-2013 (Date) rachel@nelleycompany.com (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

STATE OF TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY
500 Deaderick Street
Suite 850
Nashville, Tennessee 37243
741-2364

March 20, 2013

Rachel C. Nelley
Nelley & Company, PLLC
PO Box 150731
Nashville, TN 37215

RE: Certificate of Need Application CN1303-006
Medical Care, PLLC

Dear Ms. Nelley:

This will acknowledge our March 13, 2013 receipt of your application for the initiation of magnetic resonance imaging (MRI) services of the patients of Medical Care, PLLC and acquisition of a MRI unit at 1500 West Elk Avenue, Elizabethton (Carter County), Tennessee 37643.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 4:00 PM, Tuesday, March 26, 2013. If the supplemental information requested in this letter is not submitted by or before this time, consideration of this application may be delayed into a later review cycle.

---

1. **Section A, Applicant Profile, Item 12**

   Please respond to this question as Yes, No or N/A.

2. **Section A, Project Description, Item 13**

   The applicant has responded to this question in Attachment A.13. Please answer this question by responding underneath the question without an attachment. Please submit a replacement page.

3. Section B, Project Description, Item I.

Please indicate if the PLLC or LLC provides CT services. If yes, is the CT registered in the Health Services and Development Equipment registry?

Please document the waiting time for MRI patients in the service area. Please detail the methodology used in determining the average time patients are waiting for MRI services.

The applicant has made several statements regarding Mountain States Health Alliance not accepting CIGNA insurance in the application. Please provide documentation that supports this statement.

Please indicate if Mountain States Health Alliance accepts CIGNA insurance as out of network.

The applicant states Mountain States Health Alliance requires 50% up-front payments for MRI services. Is the 50% payment requirement calculated on MRI gross charges, net charges, deductible, or is it 50% of the patients out-of-pocket responsibility?

Please clarify is Mountain States Health Alliance requires Medicare and TennCare to pay 50% up-front payments.

Also, please provide a number of how many people in the proposed service area are enrolled with CIGNA insurance.

The applicant states 15% of the patients of the Medical Care, PLLC patients have CIGNA insurance. How many patients does this represent?

The applicant states multiple patients choose to forego recommended diagnostic imaging due to the large up-front payment required by Mountain States Health Alliance. How many people per year is the applicant speaking of in this statement and how was that total calculated?

How many of the applicant's patients fall into the category of uninsured or insured with high deductible and/or copayment?

Please indicate the locations of Medical Care PLLC in the proposed service area.

Please complete the following chart indicating the number of physician specialties and extenders at each Medical Care PLLC location:

Location	Family Practice	General Practice	Internal Medicine	General Surgery	Gynecology	Pediatrics	Other
1500 West Elk Avenue,							

Elizabethton							

The applicant proposes initiation of a 1.5 Tesla MRI. Does the applicant ever plan to refer patients to a provider with a 3.0 tesla MRI for a more complex scan? Also, is a 1.5 Tesla MRI appropriate for all medical scans?

Please indicate if the proposed MRI will be limited to the patients of the physicians within the PLLC.

4. **Section B, Project Description, Item II.C.**

The chart on page 10 of the average MRI gross charges is noted. What causes gross charges to be different from one provider to another? What is the impact of gross charges on consumers when there is a contracted insurance rate involved?

5. **Section B, Project Description, Item II.E.3**

Please discuss the quality of service from an MRI scanner that is 8 years old and that the applicant believes has at least 7+ years of useful life. How does this scanner compare in quality and resolution of a scan in comparison to a new 1.5T MRI scanner. Please note that review of the HSDA Medical Equipment Registry for the past six years indicates that the median turnaround time in replacing MRI equipment is between 7 and 8 years.

The MRI Purchase and Sale Agreement are noted. However, on page 3 of the document the purchase and sale agreement states, "Purchaser shall return an executed Agreement to OI Service on or before March 1, 2013, along with a deposit of $199,700.00 (30% of Purchase Price). If Purchaser fails to execute this agreement and pay the deposit prior to such date, the terms and conditions set forth in this agreement shall be null and void". Please indicate if the applicant has already purchased the MRI. If not, please clarify the status of the proposed MRI purchase.

Also, the document states the equipment will be delivered on or before June 1, 2013. Prior to the Agency decision. The agency meeting for this project is June 26, 2013. Please clarify.

6. **Section B, Project Description Item III.A. (Plot Plan)**

The words in the shaded areas are not legible. Please submit a legible plot plan with the location of the proposed MRI clearly marked.

7. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (2)**

Overall, what is the percentage of the proposed service area population that is accessible to the proposed MRI location?

8. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (3)**

   Please indicate the Tesla strength of the MRI located at Sycamore Shoals Hospital in Carter County.

9. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (4)**

   The applicant states the combined average utilization of existing MRI providers in all of the counties in the service area in 2011 was 1,821 procedures. The applicant also states the existing providers in the proposed service area were near 80% of the total capacity of 3600 procedures, or 2,880 procedures. It appears 1,821 procedures is not close to the standard of 2,880 procedures. Please clarify.

10. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (7) (d)**

    Please indicate how the ACR Practice Guidelines for Performing and Interpreting Magnetic Resonance Imaging (MRI) meets the establishment that assure that all MRI procedures performed are medically necessary and not unnecessarily duplicate other services.

11. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging)(7)(g)**

    The applicant states IPC, a local hospitalist group, will be used for any hospital admissions. Indian Path Medial Center is not listed as a facility to admit patients by IPC in their letter in the attachment. Is IPC contracted with all hospitals in the proposed service area?

    What is the advantage of using the hospitalist model to admit patients rather than having transfer agreements?

12. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (7) (H)**

    Please provide a brief description of National Diagnostic Imaging (NDI) and where they are located. Please indicate if NDI will use Teleradiology in reviewing MRI scans.

13. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging)(9)(a)**

    Please provide documentation that Carter, Johnson, Unicoi and Washington counties are designated at medical underserved areas (MUA). Does this mean certain zip codes are designated an MUA or is the whole county an MUA? Please clarify.

14. Section C, Need Item 3

The county names in the shaded areas of the proposed service area county map are not legible. Please submit a map with legible names of counties in the proposed service area.

15. Section C, Need Item 4.A

Your response to this item is noted. Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area.

Variable	*Carter*	*Johnson*	*Unicoi*	*Sullivan*	*Washington*	*Service Area*	*Tennessee*
Current Year (CY), Age 65+							
Projected Year (PY), Age 65+							
Age 65+, % Change							
Age 65+, % Total (PY)							
CY, Total Population							
PY, Total Population							
Total Pop. % Change							
TennCare Enrollees							
TennCare Enrollees as a % of Total Population							
Median Age							
Median Household Income							
Population % Below Poverty Level							

16. Section C, Need. Item 5

The MRI utilization table on page 32 is noted. Please provide totals for 2009, 2010 and 2011 for the proposed service area and resubmit.

17. Section C, Need, Item 6

Please provide letters from physicians practicing in the proposed service area that documents referral sources for the projected MRI utilization.

18. Section C. Economic Feasibility Item 2 (Funding)

The letter dated January 2, 2013 from Mr. Steve Hopland of State of Franklin Bank indicating a willingness to loan the $675,000 is noted. The total project cost is $838,543. How will the additional $163,543 be funded?

Also, please provide a revised funding letter. The letter states "acceptance of these terms and conditions are required by February 15, 2013 and closed by March 15, 2013."

19. Section C. Economic Feasibility Item 4 Historical and Projected Data Charts

Please complete revised Historical and Projected Data Charts that have fields for management fees. The revised charts are included with these supplemental questions.

There appears to be calculation errors in the Historical Data Chart. Please recheck and resubmit if necessary.

20. Section C. Economic Feasibility Item 6.A

The table for average gross chart, average projected deduction, average projected net charges, etc. is noted. The figures appear to not match the projected data chart totals. Please recheck and resubmit a replacement page if necessary.

21. Section C. Economic Feasibility Item 6.B

Please compare charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

The applicant notes a substantial 92% average gross charge rate increase by Mountain State Health Alliance as compared to facilities not owned by Mountain States Health Alliance. Please explain why the 92% increase.

In a scenario of a patient's insurance being contracted with every provider in the service area for an MRI at the same rate, would it matter what the gross charges are?

22. Section C. Economic Feasibility Item 10

The applicant has provided a consolidated balance sheet and income statement for Medical Care PLLC and Pine Palms Management, LLC. Since the applicant is Medical Care, PLLC, please provide the most recent balance sheet and income statement for that entity.

23. Section C. Orderly Development, Item 8 and 9

Items 8 and 9 are applicable to this project. Please provide a response.

24. Proof of Publication

The application copy did not include the publication of intent. Please provide a copy.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the

agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is May 17, 2013. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. ɜ 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Phillip M. Earhart
Health Services Examiner

PME/Enclosure

STATE OF TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY
500 Deaderick Street
Suite 850
Nashville, Tennessee 37243
741-2364

April 2, 2013

Rachel C. Nelley
Nelley & Company, PLLC
PO Box 150731
Nashville, TN 37215

RE: Certificate of Need Application CN1303-006
Medical Care, PLLC

Dear Ms. Nelley:

This will acknowledge our March 28, 2013 receipt of your supplemental response for the initiation of magnetic resonance imaging (MRI) services of the patients of Medical Care, PLLC and acquisition of a MRI unit at 1500 West Elk Avenue, Elizabethton (Carter County), Tennessee 37643.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 4:00 PM, Monday, April 8, 2013. If the supplemental information requested in this letter is not submitted by or before this time, consideration of this application may be delayed into a later review cycle.

---

1. **Section C. Economic Feasibility Item 4**

   Please specify other expenses in the Projected Data Chart listed in D. Operating Expenses 9. Other Expenses. Also, please remove reference to page 23. If needed, a blank Projected Data Chart is enclosed.

2. **Section C. Economic Feasibility Item 5**

Please recalculate the average deduction from operating revenue and average net charge on page 36 and resubmit a replacement page. Please include contractual deductions in your calculation.

3. **Section C. Economic Feasibility Item 6.A**

   The table for average gross chart, average projected deduction, average projected net charges, etc. on page 36 of the application is noted. The figures appear to not match the projected data chart totals. Please recheck and include the changes on the same replacement page as referenced in the previous question.

4. **Section C. Economic Feasibility Item 8**

   The applicant documents project financial viability on page 39 by stating net operating income less capital expenditures is projected to be $978,024 in Year One and $1,023,856 In Year 2 in the Projected Chart. These totals do not match figures in the supplemental Projected Data Chart that includes management fees of $661,434 in Year One and $691,414 in Year Two. Please correct and submit a replacement page 39.

5. Section C. Orderly Development, Item 8 and 9

   The applicant responded to items 8 and 9 of the Economic Feasibility section rather than the requested items of items 8 and 9 in the Orderly Development section on page 44 of the application. Please provide a response.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is May 17, 2013. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first

day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. ə 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Phillip M. Earhart
Health Services Examiner

PME/Enclosure

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in _____ (Month).

		Year____	Year____	Year____
A.	Utilization Data (Specify unit of measure)	_____	_____	_____
B.	Revenue from Services to Patients			
1.	Inpatient Services	$_____	$_____	$_____
2.	Outpatient Services	_____	_____	_____
3.	Emergency Services	_____	_____	_____
4.	Other Operating Revenue (Specify)_____	_____	_____	_____
	Gross Operating Revenue	$_____	$_____	$_____
C.	Deductions from Gross Operating Revenue			
1.	Contractual Adjustments	$_____	$_____	$_____
2.	Provision for Charity Care	_____	_____	_____
3.	Provisions for Bad Debt	_____	_____	_____
	Total Deductions	$_____	$_____	$_____
NET OPERATING REVENUE		$_____	$_____	$_____
D.	Operating Expenses			
1.	Salaries and Wages	$_____	$_____	$_____
2.	Physician's Salaries and Wages	_____	_____	_____
3.	Supplies	_____	_____	_____
4.	Taxes	_____	_____	_____
5.	Depreciation	_____	_____	_____
6.	Rent	_____	_____	_____
7.	Interest, other than Capital	_____	_____	_____
8.	Management Fees:			
a.	Fees to Affiliates	_____	_____	_____
b.	Fees to Non-Affiliates	_____	_____	_____
9.	Other Expenses – Specify	_____	_____	_____
	Total Operating Expenses	$_____	$_____	$_____
E.	Other Revenue (Expenses) – Net (Specify)_____	$_____	$_____	$_____
NET OPERATING INCOME (LOSS)		$_____	$_____	$_____
F.	Capital Expenditures			
1.	Retirement of Principal	$_____	$_____	$_____
2.	Interest	_____	_____	_____
	Total Capital Expenditures	$_____	$_____	$_____
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$_____	$_____	$_____

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in _____ (Month).

		Year_____	Year_____
A.	Utilization Data (Specify unit of measure)	_____	_____
B.	Revenue from Services to Patients		
	1. Inpatient Services	$_____	$_____
	2. Outpatient Services	_____	_____
	3. Emergency Services	_____	_____
	4. Other Operating Revenue (Specify)_____	_____	_____
	Gross Operating Revenue	**$**_____	**$**_____
C.	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$_____	$_____
	2. Provision for Charity Care	_____	_____
	3. Provisions for Bad Debt	_____	_____
	Total Deductions	**$**_____	**$**_____
NET OPERATING REVENUE		**$**_____	**$**_____
D.	Operating Expenses		
	1. Salaries and Wages	$_____	$_____
	2. Physician's Salaries and Wages	_____	_____
	3. Supplies	_____	_____
	4. Taxes	_____	_____
	5. Depreciation	_____	_____
	6. Rent	_____	_____
	7. Interest, other than Capital	_____	_____
	8. Management Fees:		
	a. Fees to Affiliates	_____	_____
	b. Fees to Non-Affiliates	_____	_____
	9. Other Expenses – Specify	_____	_____
	Total Operating Expenses	**$**_____	**$**_____
E.	Other Revenue (Expenses) -- Net (Specify)_____	$_____	$_____
NET OPERATING INCOME (LOSS)		**$**_____	**$**_____
F.	Capital Expenditures		
	1. Retirement of Principal	$_____	$_____
	2. Interest	_____	_____
	Total Capital Expenditures	**$**_____	**$**_____
NET OPERATING INCOME (LOSS)			

LESS CAPITAL EXPENDITURES $_____ $_____

HISTORICAL DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year____	Year___	*Year*_____
1.	$_____	$_____	$_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
Total Other Expenses	$_____	$_____	$_____

PROJECTED DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year____	Year___
1.	$_____	$_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
Total Other Expenses	$_____	$_____

COPY-

SUPPLEMENTAL-1

Medical Care, PLLC

CN1303-006

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

Rachel C. Nelley, Attorney
rachel@nelleycompany.com
615.274.4838

March 27, 2013

VIA HAND DELIVERY

Phillip M. Earhart
Health Services Examiner
TN Health Services and Development Agency
500 Deaderick Street, Suite 850
Nashville, TN 37243

Re: Certificate of Need Application CN1303-006
Medical Care, PLLC

Dear Mr. Earhart:

This letter will serve to follow up the filing of the above-referenced certificate of need application and is submitted as a first supplemental response to your e-mail correspondence dated March 20, 2013, wherein additional information or clarification was requested.

1. **Section A, Applicant Profile, Item 12**

   Please respond to this question as Yes, No or N/A.

   Response: *A replacement page 3 responding to the question "N/A" is enclosed.*

2. **Section A, Project Description, Item 13**

   The applicant has responded to this question in Attachment A.13. Please answer this question by responding underneath the question without an attachment. Please submit a replacement page.

   Response: *There is no space remaining available on the submitted page 3 to respond underneath the question. The enclosed requested replacement page is identified as page 3.A.*

3. **Section B, Project Description, Item I.**

Please indicate if the PLLC or LLC provides CT services. If yes, is the CT registered in the Health Services and Development Equipment registry?

Response: *Yes, Medical Care, PLLC does provide CT services to its patients and has registered the CT in the Health Services and Development Equipment registry.*

Please document the waiting time for MRI patients in the service area. Please detail the methodology used in determining the average time patients are waiting for MRI services.

Response: *Medical Care, PLLC does not have direct access to actual MRI wait times, but reviewed its most recent MRI order dates and compared the order dates to the scheduled dates over the past 3 months. The minimum wait time for non-emergent MRI is 3 days to accommodate MSHA financial clearance. See attached MSHA policy. The average time from date ordered to completed over the past 3 months is 10 days.*

The applicant has made several statements regarding Mountain States Health Alliance not accepting CIGNA insurance in the application. Please provide documentation that supports this statement.

Response: *The requested documentation is enclosed and includes a printed excerpt from the Mountain States Health Alliance ("MSHA") website indicating that MSHA is not a CIGNA network provider.*

Please indicate if Mountain States Health Alliance accepts CIGNA insurance as out of network.

Response: *CIGNA patients are able to access MSHA facilities as out of network, but at a much higher cost.*

The applicant states Mountain States Health Alliance requires 50% up-front payments for MRI services. Is the 50% payment requirement calculated on MRI gross charges, net charges, deductible, or is it 50% of the patients out-of-pocket responsibility?

Response: *Per the enclosed MSHA pre-payment policy, MSHA requires payment of one-half of a patient's total out of pocket expense.*

Please clarify is Mountain States Health Alliance requires Medicare and TennCare to pay 50% up-front payments.

Response: *Per the enclosed MSHA pre-payment policy, "the insured population" as well as the "uninsured population" are required to pre-pay half of the patient's total out-of-pocket expense for all non-emergency procedures. If Medicare or TennCare patients have any out-*

of-pocket expenses associated with a non-emergency MRI scan, then the MSHA prepayment policy would apply.

Also, please provide a number of how many people in the proposed service area are enrolled with CIGNA insurance.

Response: *The requested information is not available to the Applicant. As indicated in the Applicant's CON application, approximately 15% of the Medical Care, PLLC patients with private insurance have CIGNA. The applicant has been given the estimate of 15,000 - 20,000 CIGNA patients within the service are.*

The applicant states 15% of the patients of the Medical Care, PLLC patients have CIGNA insurance. How many patients does this represent?

Response: *Medical Care, PLLC currently has 1,777 patients with CIGNA insurance.*

The applicant states multiple patients choose to forego recommended diagnostic imaging due to the large up-front payment required by Mountain States Health Alliance. How many people per year is the applicant speaking of in this statement and how was that total calculated?

Response: *The applicant searched its patient records for patients for whom an MRI was ordered but never done. This query resulted in 26 patients not having an MRI that was ordered over the past 3 months or an estimated 104 patients annually. This does not include any patients who would have had an MRI ordered, but, after discussion with the physician, chose not to have the study. In these cases, the MRI was never ordered within the practice's electronic medical record system, so the query would not have found them. The number of patients this applies to is unknown but several physicians in the practice estimated that it happens a couple times per month (per provider). This would add a couple hundred additional MRI studies that were recommended, but not completed or delayed due to the high up-front cost.*

How many of the applicant's patients fall into the category of uninsured or insured with high deductible and/or copayment?

Response: *Medical Care, PLLC does not categorize/track patients by the amount of their deductible or copayment and, therefore, cannot provide HSDA with a specific number. Medical Care, PLLC does track patients who list cash or uninsured. The practice has 26,349 cash pay or uninsured patients.*

Please indicate the locations of Medical Care PLLC in the proposed service area.

Response: *Medical Care, PLLC has offices in the following locations, all of which are within the service area:*

1500 West Elk Ave, Elizabethton, TN 37643
401 East Main Street, Johnson City, TN 37601
437 Hwy 321, Hampton, TN 37658

Please complete the following chart indicating the number of physician specialties and extenders at each Medical Care PLLC location:

Location	Family Practice	General Practice	Internal Medicine	General Surgery	Gynecology	Pediatrics	Other
1500 West Elk Avenue, Elizabethton	5			1	1	1	8
401 East Main Sreet, Johnson City	6		2			1	6
437 Hwy 321, Hampton		1					1

The applicant proposes initiation of a 1.5 Tesla MRI. Does the applicant ever plan to refer patients to a provider with a 3.0 tesla MRI for a more complex scan? Also, is a 1.5 Tesla MRI appropriate for all medical scans?

Response: *The Applicant anticipates that the 1.5 Tesla MRI is sufficient for all the scans ordered by its primary care providers and does not anticipate that it will be necessary for its providers to order 3.0 Tesla scans. 3.0 Tesla scans would typically be ordered by sub specialist on patients they are treating directly.*

Please indicate if the proposed MRI will be limited to the patients of the physicians within the PLLC.

Response: *Yes, the proposed MRI will be limited to the patients of the physicians within the PLLC. The Applicant is NOT seeking a certificate of need to establish an outpatient diagnostic center.*

4. **Section B, Project Description, Item II.C.**

The chart on page 10 of the average MRI gross charges is noted. What causes gross charges to be different from one provider to another? What is the impact of gross charges on consumers when there is a contracted insurance rate involved?

Response: *Gross charges reflect a provider's full, undiscounted charge. Determining the amount of the gross charge is purely a matter of individual provider preference and may be*

based on any number of factors not necessarily reflecting the actual cost of providing a service.

While a provider may bill its gross charge, the amount the provider actually collects depends in large part on the payer from which it accepts payment. Gross charges are subject to discounts that third-party payers negotiate or are totally disregarded in the case of payers who negotiate flat fees. Patients who self-pay, are underinsured or are uninsured have little to no bargaining power and typically pay full, non-discounted gross charges. Patients whose insurance payment rates are linked to charges because services are not governed by fee schedules or other fixed payment amounts (i.e., a percentage discount on hospital charges) are also affected by high gross charges because the amount of co-insurance the patient is required to pay will be higher (i.e., in an 80/20 plan, insurance will pay 80% of the charge for the medical service and the patient is responsible for paying the remaining 20% after meeting his or her deductible). Large insurance companies with relatively more market power vis-a-vis doctors and hospitals usually pay lower prices for given services than do smaller insurers with less market power. Accordingly, even if a patient has a contracted insurance rate that reflects a discount, he/she will pay more in the form of coinsurance in the face of a higher gross charge, particularly when his/her insurer is a small one with less bargaining power and is not in a position to negotiate a larger discount.

5. **Section B, Project Description, Item II.E.3**

Please discuss the quality of service from an MRI scanner that is 8 years old and that the applicant believes has at least 7+ years of useful life. How does this scanner compare in quality and resolution of a scan in comparison to a new 1.5T MRI scanner. Please note that review of the HSDA Medical Equipment Registry for the past six years indicates that the median turnaround time in replacing MRI equipment is between 7 and 8 years.

Response: *The GE ExciteCKX4 magnet in the MRI is the same magnet that GE offers on their new MRI systems. So the quality of the magnet is exactly the same as new. The only changes are the computers (keep getting faster) and the software. This MRI is upgradeable to the latest current version (same as new). For the basic MRI studies and patient flow that anticipated by the practice, the older version software has equivalent quality and resolution. The newer software version can increase scan speed and post processing, but is not required for the practice's application.*

The MRI Purchase and Sale Agreement are noted. However, on page 3 of the document the purchase and sale agreement states, "Purchaser shall return an executed Agreement to OI Service on or before March 1, 2013, along with a deposit of $199,700.00 (30% of Purchase Price). If Purchaser fails to execute this agreement and pay the deposit prior to such date, the terms and conditions set forth in this agreement shall be null and void". Please indicate

if the applicant has already purchased the MRI. If not, please clarify the status of the proposed MRI purchase.

Also, the document states the equipment will be delivered on or before June 1, 2013. Prior to the Agency decision. The agency meeting for this project is June 26, 2013. Please clarify.

Response: *The Applicant has not yet purchased the proposed MRI and will not do so unless and until it obtains approval of its certificate of need application from HSDA. Preparation of the Applicant's certificate of need application took more time than expected. A revised purchase agreement is enclosed that reflects an execution and deposit deadline and delivery date that occur after the date that HSDA meets to consider the Applicant's certificate of need application.*

6. **Section B, Project Description Item III.A. (Plot Plan)**

The words in the shaded areas are not legible. Please submit a legible plot plan with the location of the proposed MRI clearly marked.

Response: Revised plot plans are enclosed.

7. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (2)**

Overall, what is the percentage of the proposed service area population that is accessible to the proposed MRI location?

Response: *(45.79% + 37.71% + 5.68% + 3.88% + 3.28%) = 93.34%*

10,754 (45.79%) of the patients resided in Carter County. 8,856 (37.71%) of the patients resided in Washington County. 1,333 (5.68%) of the patients resided in Sullivan County. 911 (3.88%) of the patients resided in Johnson County. 771 (3.28%) of the patients resided in Unicoi County. 858 (3.65%) of the patients resided outside the proposed service area.

8. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (3)**

Please indicate the Tesla strength of the MRI located at Sycamore Shoals Hospital in Carter County.

Response: *According to the medical equipment registry maintained by HSDA and dated September 11, 2012, the Tesla strength of the MRI located at Sycamore Shoals Hospital in Carter County is 1.5.*

9. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (4)**

The applicant states the combined average utilization of existing MRI providers in all of the counties in the service area in 2011 was 1,821 procedures. The applicant also states the existing providers in the proposed service area were near 80% of the total capacity of 3600 procedures, or 2,880 procedures. It appears 1,821 procedures is not close to the standard of 2,880 procedures. Please clarify.

Response: *The combined average utilization figure of 1,821 procedures is incorrect. According to the latest available data from the Health Services and Development Agency, in 2011, the average combined utilization was much higher than 1,821 and closer to the standard of 2,880 procedures. The average combined utilization could be calculated one of two ways. One way includes the mobile unit operating 2 days per month at Johnson County Community Hospital as a full unit. Counting the part-time mobile unit as a full unit results in a combined average utilization in 2011 of 2,381 (52389 ÷22). A more accurate calculation, however, would not count the part-time mobile unit as a full unit. If the part-time mobile unit is counted as 0.1 of a fixed unit, then the average combined utilization in 2011 was 2,483 (52,389 ÷21.1).*

The 2,483 average combined utilization figure for 2011 includes two units in Sullivan County who also appear to be operating on a part-time basis, namely, Appalachian Orthopaedic Associates, PC, an extremity MRI, whose utilization in 2011 was 288 procedures, and Sapling Grove Imaging, LLC (Wellmont), a stand-up, multiposition MRI, whose utilization in 2011 was 349. According to the CON application filed by Sapling Grove Imaging, LLC (CN0510-090), the standup, multiposition MRI was to be "available for subleasing up to four (4) days per week." Additionally, the 2,483 average combined utilization figure for 2011 includes an extremity MRI in Washington County also owned by Appalachian Orthopaedic Associates, PC. Inclusion of these "specialty MRI units" as full units in the calculation of combined average utilization does not seem appropriate. Accordingly, the Applicant submits that the calculation of combined average utilization should either exclude these three (3) units or not count them as full units. If the 3 units and their utilization are excluded entirely, then the combined average utilization of the service area in 2011 was 2,829 (51206÷18.1), which is greater than the 2,880 procedure threshold.

10. Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (7) (d)

Please indicate how the ACR Practice Guidelines for Performing and Interpreting Magnetic Resonance Imaging (MRI) meets the establishment that assure that all MRI procedures performed are medically necessary and not unnecessarily duplicate other services.

Response: *The Applicant submits that the ACR Practice Guidelines serve as acceptable professional reference materials for ensuring the medical appropriateness and necessity of MRI scans. Nevertheless, Medical Care, PLLC agrees with the American College of Radiology (ACR) that "the ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented." In addition to referring to the ACR practice guidelines, which are intended by the ACR as "an educational tool designed to assist practitioners in providing appropriate radiologic care for patients," Medical Care, PLLC will ensure that all MRI studies require a physician order and require that these orders be attached to an appropriate diagnosis code ICD-9 to justify the order. Further, all payers require prior*

authorization prior to conducting the MRI study. This prior authorization helps to maintain the requirement for medical necessity. Moreover, National Diagnostic Imaging (NDI) the radiologist group which Medical Care, PLLC will utilize for interpreting the MRI studies, has an internal utilization review process outside of Medical Care, PLLC to monitor for unnecessary studies.

On reduction of duplication, Medical Care, PLLC is participating in One Partner, the local health information exchange (HIE), which will allow Medical Care, PLLC physicians to review diagnostic studies done at other participating service providers. This increased knowledge through access of outside diagnostic studies will reduce the unnecessary duplication of similar diagnostic services.

11. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging)(7)(g)**

The applicant states IPC, a local hospitalist group, will be used for any hospital admissions. Indian Path Medical Center is not listed as a facility to admit patients by IPC in their letter in the attachment. Is IPC contracted with all hospitals in the proposed service area?

Response: *IPC is not contracted with all hospitals in the proposed service area – it does not admit to Indian Path Medical Center, but does admit to Holston Valley, both within Kingsport.*

What is the advantage of using the hospitalist model to admit patients rather than having transfer agreements?

Response: *Medical Care, PLLC is a private physician practice and is not a facility. The requirement for transfer agreements typically only apply to facilities. Medical Care, PLLC is unaware of any requirement by the Board of Medical Examiners to have a transfer agreement in place. Medical Care, PLLC patients are followed in the hospital by IPC, the local hospitalist group which specializes in in-patient care. IPC is also participating in One Partner, the local health information exchange (HIE) along with Qualuable, a Medicare approved ACO / MSSP. Both of these increase patient coordination and efficiency and quality.*

12. **Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging) (7) (H)**

Please provide a brief description of National Diagnostic Imaging (NDI) and where they are located. Please indicate if NDI will use Teleradiology in reviewing MRI scans.

Response: *Yes, NDI intends to use teleradiology via PACS technology in reviewing MRI scans. As stated in the application, NDI radiologists are board certified, fellowship trained and licensed in Tennessee. Several have subspecialty in MRI and specifically in neuroradiology. The radiologists meet continuing medical education requirements and maintain current Tennessee licenses. NDI is located in Beachwood, Ohio. The company has been providing subspecialty teleradiology services to hospitals, imaging centers, office-based imaging practices and outpatient clinics nationwide since 2003.*

13. Section C, Need, Item 1.a. (Service Specific Criteria-Magnetic Resonance Imaging)(9)(a)

Please provide documentation that Carter, Johnson, Unicoi and Washington counties are designated at medical underserved areas (MUA). Does this mean certain zip codes are designated an MUA or is the whole county an MUA? Please clarify.

Response: *The MUA designation applies to the whole county of Carter, the whole county of Unicoi and the whole county of Johnson. With respect to Washington County, only the Bethesda Division and the Telford Division are considered MUAs. A printed version of the report generated by the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA) Data Warehouse Report Tool is enclosed along with a copy of the search results for counties in the service area generated by the HRSA website and accessed on March 26, 2013 available at http://muafind.hrsa.gov/index.aspx.*

14. Section C, Need Item 3

The county names in the shaded areas of the proposed service area county map are not legible. Please submit a map with legible names of counties in the proposed service area.

Response: *Two revised maps are enclosed.*

15. Section C, Need Item 4.A

Your response to this item is noted. Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area.

Variable	*Carter*	*Johnson*	*Unicoi*	*Sullivan*	*Washington*	*Service Area*	*Tennessee*
Current Year (CY), Age 65+	*9980*	*3366*	*3629*	*29789*	*19640*	*66404*	*884505*
Projected Year (PY), Age 65+	*11274*	*3817*	*4026*	*34291*	*22373*	*75781*	*1012853*
Age 65+, % Change	*12.966%*	*13.399%*	*10.94%*	*15.113%*	*13.915%*	*14.121%*	*14.511%*
Age 65+, % Total (PY)	*19.51%*	*21.10%*	*21.87%*	*21.50%*	*16.87%*	*19.61%*	*15.33%*
CY, Total Population	*57355*	*18095*	*19127*	*156786*	*125094*	*376457*	*6456243*
PY, Total Population	*57772*	*18087*	*18412*	*159499*	*132595*	*386365*	*6607016*
Total Pop. % Change	*+73%*	*-.044%*	*-3.73%*	*+1.73%*	*+5.996%*	*+2.632%*	*+2.335%*
TennCare Enrollees	*11353*	*3960*	*3590*	*27451*	*19002*	*65356*	*1205480*
TennCare Enrollees as a % of Total Population	*19.79%*	*21.88%*	*18.77%*	*17.51%*	*15.19%*	*17.36%*	*18.67%*
Median Age	*42*	*42.7*	*44.6*	*43.2*	*39.3*	*42.36*	*37.8*
Median Household Income	*32148*	*32159*	*35265*	*40572*	*42104*	*36449.60*	*43,989*
Population % Below Poverty Level	*22%*	*23.4%*	*20.7%*	*16.5%*	*17.3%*	*21.73%*	*16.9%*

16. Section C, Need. Item 5

The MRI utilization table on page 32 is noted. Please provide totals for 2009, 2010 and 2011 for the proposed service area and resubmit.

Response: *See table below which also includes 2012 utilization for all but 3 service area providers. The remaining 3 providers' utilization for 2012 is expected to become available on March 31, 2013.*

County	Facility and Type	Number of MRI Scanners and Type	Total Procedures			
			2009	2010	2011	2012
Washington	Franklin Woods Community Hospital (HOSP)	1 Fixed	0	1635	3546	3499
Washington	Johnson City Medical Center (HOSP)	2 Fixed	5186 (avg. 2593 per scanner)	6596 (avg. 3298 per scanner)	7247 (avg. 3623.5 per scanner)	7237
Washington	Mountain States Imaging at Med Tech Parkway (ODC)	1 Fixed	2162	2066	2738	2697
Washington	Watauga Orthopaedics, PLC (PO)	1 Fixed	3284	2927	2748	2415
Washington	Appalachian Orthopaedic Associates - Johnson City (PO)	1 Fixed	639	521	546	357
Sullivan	Appalachian Orthopaedic Associates – Kingsport (PO)	1 Fixed	1396	1293	1460	Sold
Sullivan	Appalachian Orthopaedic Associates, PC (PO)	1 Fixed	400	365	288	268
Sullivan	Bristol Regional Medical Center (HOSP)	2 Fixed	5904 (avg. 2952 per scanner)	6168 (avg. 3084 per scanner)	6447 (avg. 3223.5 per scanner)	6578
Sullivan	Holston Valley Imaging Center, LLC (ODC)	3 Fixed	9367 (avg. 3122.3 per scanner)	8025 (avg. 2675 per scanner)	8362 (avg. 2787.3 per scanner)	8792
Sullivan	Holston Valley	1 Fixed	4026	3624	3774	3514

	Medical Center (HOSP)					
Sullivan	Indian Path Medical Center	1 Fixed	2697	2700	2651	3000
Sullivan	Meadowview Outpatient Diagnostic Center	1 Fixed	4440	5258	4457	n/a
Sullivan	Wellmont Sapling Grove Imaging, LLC (Stand up MRI) (HImaging)	1 Fixed	656	536	349	150
Sullivan	Sapling Grove Outpatient Diagnostic Center (ODC)	1 Fixed	2588	2116	2587	n/a
Sullivan	Volunteer Parkway Imaging Center (HODC)	1 Fixed	1279	1193	1327	1348
Unicoi	Unicoi County Memorial Hospital, Inc. (HOSP)	1 Fixed	967	959	1630	n/a
Johnson	Johnson County Community Hospital (HOSP)	1 Mobile (2 days/month)	255	256	274	308
Carter	Sycamore Shoals Hospital (HOSP)	1 Fixed	2276	2026	1958	2014
	Service Area Total Procedures		**47,522**	**48,264**	**52,389**	n/a

17. **Section C, Need, Item 6**

Please provide letters from physicians practicing in the proposed service area that documents referral sources for the projected MRI utilization.

Response: *The Applicant is a private physician practice and intends to offer MRI services primarily to patients of the medical practice and not accept referrals from outside physicians. In order to accept referrals from physicians outside the medical practice, the Applicant would have to obtain a certificate of need to establish an outpatient diagnostic center, which it has not done and is not currently requesting.*

18. **Section C. Economic Feasibility Item 2 (Funding)**

The letter dated January 2, 2013 from Mr. Steve Hopland of State of Franklin Bank indicating a willingness to loan the $675.000 is noted. The total project cost is $838,543. How will the additional $163,543 be funded?

Response: *The bank funds exceed all initial capital requirements. The facility expense and debt service will come from cash flow from operations over time.*

Also, please provide a revised funding letter. The letter states "acceptance of these terms and conditions are required by February 15, 2013 and closed by March 15, 2013."

Response: *The requested funding letter is enclosed.*

19. Section C. Economic Feasibility Item 4 Historical and Projected Data Charts

Please complete revised Historical and Projected Data Charts that have fields for management fees. The revised charts are included with these supplemental questions.

There appears to be calculation errors in the Historical Data Chart. Please recheck and resubmit if necessary.

Response: *The requested charts are enclosed.*

20. Section C. Economic Feasibility Item 6.A

The table for average gross chart, average projected deduction, average projected net charges, etc. is noted. The figures appear to not match the projected data chart totals. Please recheck and resubmit a replacement page if necessary.

21. Section C. Economic Feasibility Item 6.B

Please compare charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: *See revised table below.*

CPT	MRI	Medical Care, PLLC Gross Charge	Medicare Physician Fee Schedule
70551	MRI HEAD W/O CONTRAST	$1,400.00	437.20
70552	MRI HEAD W/ CONTRAST	$1,640.00	488.23
70553	MRI HEAD W/ & W/O CONTRAST	$2,060.00	571.93
71550	MRI CHEST W/O CONTRAST	$1,400.00	477.68
71551	MRI CHEST W CONTRAST	$1,640.00	530.76
71552	MRI CHEST W & W/O CONTRAST	$2,200.00	675.02
72141	MRI CERVICAL SPINE W/O CONTRAST	$1,250.00	387.18
72142	MRI CERVICAL SPINE W/ CONTRAST	$1,500.00	498.10
72146	MRI THORACIC SPINE W/O CONTRAST	$1,400.00	387.86

72147	MRI THORACIC SPINE W/ CONTRAST	$1,500.00	439.92
72148	MRI LUMBAR SPINE W/O CONTRAST	$1,300.00	382.08
72149	MRI LUMBAR SPINE W/ CONTRAST	$1,600.00	481.43
72156	MRI C SPINE W/ & W/O CONTRAST	$2,000.00	572.27
72157	MRI T SPINE W/ & W/O CONTRAST	$2,000.00	531.78
72158	MRI L SPINE W/ & W/O CONTRAST	$2,000.00	560.02
72195	MRI PELVIS W/O CONTRAST	$1,250.00	432.09
72196	MRI PELVIS W CONTRAST	$1,500.00	480.06
72197	MRI PELVIS W & W/O CONTRAST	$1,900.00	585.88
73218	MRI UPPER EXTREMITY W/O CONTRAST	$1,200.00	424.95
73219	MRI UPPER EXTREMITY W CONTRAST	$1,450.00	471.56
73220	MRI UPPER EXTREMITY W & W/O CONTRAST	$1,750.00	581.45
73221	MRI UPPER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73222	MRI UPPER EXTREMITY JOINT W CONTRAST	$1,400.00	442.64
73223	MRI UPPER EXTREMITY JOINT W & W/O CONTRAST	$1,900.00	548.11
73718	MRI LOWER EXTREMITY W/O CONTRAST	$1,200.00	422.23
73719	MRI LOWER EXTREMITY W CONTRAST	$1,400.00	479.38
73720	MRI LOWER EXTREMITY W & W/O CONTRAST	$1,750.00	585.20
73721	MRI LOWER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73722	MRI LOWER EXTREMITY JOINT W CONTRAST	$1,350.00	449.10
73723	MRI LOWER EXTREMITY JOINT W & W/O CONTRAST	$1,950.00	547.77
74181	MRI ABDOMEN W/O CONTRAST	$1,400.00	382.42
74182	MRI ABDOMEN W CONTRAST	$1,600.00	528.04
74183	MRI ABDOMEN W & W/O CONTRAST	$2,000.00	587.92
MEDICAL CARE, PLLC AVERAGE CHARGE PER PROCEDURE		$1,584.55	

The applicant notes a substantial 92% average gross charge rate increase by Mountain State Health Alliance as compared to facilities not owned by Mountain States Health Alliance. Please explain why the 92% increase.

Response: *MSHA charges and collects higher fees as compared to alternate service providers likely due to the lack of competition in the service area.*

In a scenario of a patient's insurance being contracted with every provider in the service area for an MRI at the same rate, would it matter what the gross charges are?

Response: *IF all payer contracted at the same flat rate then no, but payers contract at vastly different rates for similar services from different service providers. So unless there is a single flat rate payer it DOES matter what service providers charge and collect for their services.*

22. **Section C. Economic Feasibility Item 10**

The applicant has provided a consolidated balance sheet and income statement for Medical Care PLLC and Pine Palms Management, LLC. Since the applicant is Medical Care, PLLC, please provide the most recent balance sheet and income statement for that entity.

Response: *The requested balance sheet and income statement are enclosed. Medical Care, PLLC is set up to break even at the end on the year. Any true gains or losses are passed through Pine Palms Management, LLC and then through the individual owners' returns.*

23. Section C. Orderly Development, Item 8 and 9

Items 8 and 9 are applicable to this project. Please provide a response.

Response: *A response to these items was included with the application and is set forth below:*

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Revenue and expense information for this proposal for Years 1 and 2 following project completion is included in the Projected Data Chart. The net operating income less capital expenditures as represented is projected to be $978,024 in year 1 and $1,023,856 in year 2.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Medical Care, PLLC is both a TennCare and Medicare provider. In the previous year, during the period November 20, 2011 to November 20, 2012, 31.24% of the patients treated at Medical Care, PLLC were TennCare enrollees. During the same period, 9.49% of the patients were on Medicare. Private insurance accounted for 38.55% of the patients, Worker's Compensation accounted for

5.36% of the patients and private pay accounted for 14.71% of the patients. Medical Care, PLLC anticipates seeing a similar payor mix in the future.

The estimated dollar amount of revenue and percentage of total project revenue anticipated from TennCare and Medicare for the proposals first year of operation is set forth below (note that Medical Care, PLLC typically sees TennCare and Medicare patients more frequently than other patient populations because they tend to have more chronic conditions. Accordingly, the percentage of anticipated revenue from TennCare and Medicare reflected below is higher than the percentage of patients noted above. The percentage of anticipated revenue is based on the medical practice's current percentage of TennCare/Medicare revenue for patient visits.):

	TennCare	Medicare
Gross TennCare and Medicare MRI Revenues	$1,359,000.34	$1,214,797.73
% of Total MRI Revenues	31.1%	27.8%

24. Proof of Publication

The application copy did not include the publication of intent. Please provide a copy.

Response: *The publication affidavit from the newspaper as proof of the publication of the letter of intent is enclosed. A copy was included with the application copy as required.*

Should you have any questions or require additional information pertaining to this application, please do not hesitate to contact me by telephone at 615.274.4838 or by e-mail at rachel@nelleycompany.com.

Very truly yours,

Rachel C. Nelley
Attorney

Attachments
cc: Steve Hopland, Medical Care, PLLC

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

AFFIDAVIT

2013 MAR 28 AM 9:50

STATE OF TENNESSEE

COUNTY OF Carter

NAME OF FACILITY: MEDICAL CARE, PLLC

I, ARNOLD O HOWARD after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 26 day of March, 2013, witness my hand at office in the County of Carter, State of Tennessee.

NOTARY PUBLIC

My commission expires 10-21-2015,

HF-0043

Revised 7/02

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

		Current Beds Licensed	*CON	Staffed Beds	Beds Proposed	TOTAL Beds at Completion
A.	Medical					
B.	Surgical					
C.	Long-Term Care Hospital					
D.	Obstetrical					
E.	ICU/CCU					
F.	Neonatal					
G.	Pediatric					
H.	Adult Psychiatric					
I.	Geriatric Psychiatric					
J.	Child/Adolescent Psychiatric					
K.	Rehabilitation					
L.	Nursing Facility (non-Medicaid Certified)					
M.	Nursing Facility Level 1 (Medicaid only)					
N.	Nursing Facility Level 2 (Medicare only)					
O.	Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P.	ICF/MR					
Q.	Adult Chemical Dependency					
R.	Child and Adolescent Chemical Dependency					
S.	Swing Beds					
T.	Mental Health Residential Treatment					
U.	Residential Hospice					
	TOTAL					

*CON-Beds approved but not yet in service

10. **Medicare Provider Number** 3373580
Certification Type Physician Group Practice

11. **Medicaid Provider Number** 1512986
Certification Type Physician Group Practice

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?** N/A

13. ***Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.*** **Will this project involve the treatment of TennCare participants?** Yes **If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted *or plans to contract.***
The MCOs with which the applicant has contracted are identified on the next page (Page 3-A).

Discuss any out-of-network relationships in place with MCOs/BHOs in the area. See page 3-A.

Section A, Applicant Profile

13. Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.

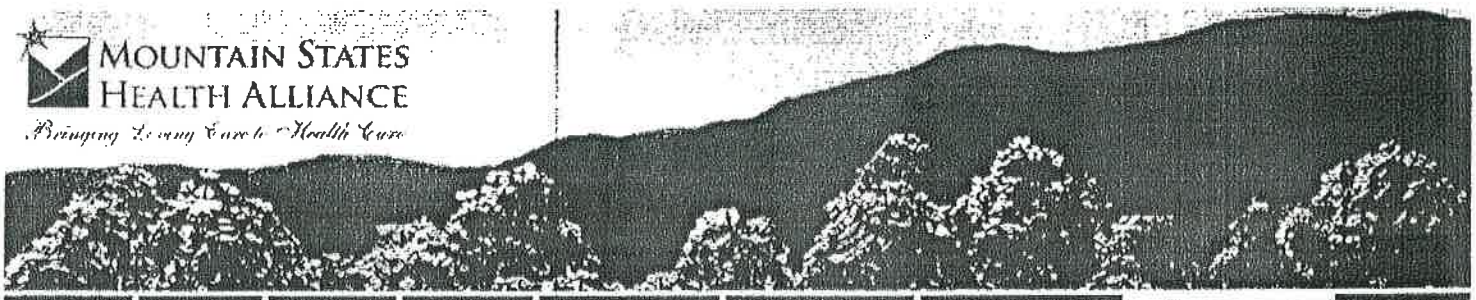
The TennCare MCOs operating in the proposed service area (Carter, Washington, Sullivan, Johnson and Unicoi Counties) are BlueCare, TennCare Select and UnitedHealthcare Community Plan.

Will this project involve the treatment of TennCare participants?

Yes.

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

The Applicant has contracts with BlueCare, TennCare Select and UnitedHealthcare Community Plan.



MOUNTAIN STATES HEALTH ALLIANCE
Bringing Loving Care to Health Care

MSHA Insurance Provider Information

Will you have access to MSHA hospitals and physicians Jan. 1, 2012?

Beginning Jan. 1, 2012, **CIGNA** will no longer include **Mountain States Health Alliance hospitals**, physicians and outpatient clinics in its network. This decision may make it difficult for many people in our region to find health care services close to home. However, all of the other **health plans and provider networks** in our region include MSHA facilities and physicians in their networks and are listed to the right.

Mountain States Health Alliance hospitals and facilities include:

Tennessee Hospitals

- Franklin Woods Community Hospital
- Indian Path Medical Center
- James H. & Cecile C. Quillen Rehabilitation Hospital
- Johnson City Medical Center
- Johnson County Community Hospital
- Sycamore Shoals Hospital
- Woodridge Hospital

Virginia Hospitals

- Dickenson Community Hospital
- Johnson Memorial Hospital
- Norton Community Hospital
- Russell County Medical Center
- Smyth County Community Hospital

Physicians, Clinics and Other Services

Mountain States Health Alliance Insurance Company and Provider Networks

A
- Aetna
- Anthem Blue Cross and Blue Shield

B
- Beech Street Network
- BlueCross® BlueShield® of Tennessee

C
- Coalition America/NPPN/PCA
- Coventry National Healthcare Network/First Health
- CrestPoint Health

F
- Fortified Provider Network

G
- Gateway Health

H
- Humana

I
- The Initial Group, Inc.
- Integrated Health Plan (IHP)
- Integrated Solutions Health Network LLC

M
- Magellan Health Services

SUPPLEMENTAL - #1
March 28, 2013
9:46 am

- Mountain States Medical Group
- with primary and speciality group practices
- Abingdon Physician Partners (APP) Community Physicians
- First Assist Urgent Care Centers
- Medical Center HomeCare and Hospice
- and Mediserve services throughout the Tri-Cities region

Questions?

If you have any questions regarding your personal or business health plan network and Mountain States Health Alliance, please call 423-431-6647 for more information.

www.msha.com/insurance

- Magellan Health Services
- Medicare
- MultiPlan Network

N

- NovaNet Inc.

O

- One Call Medical (Norton, Va.)
- Optima Health
- OptumHealth Behavioral Solutions/United Behavioral Health

P

- PHCS Network

U

- UMWA Funds
- UnitedHealthcare

V

- Virginia Health Network
- Virginia Medicaid
- Virginia Premier Health Plan Inc.

MOUNTAIN STATES HEALTH ALLIANCE

7/30/2012

To our fellow physicians:

As you are aware, we in the health care industry face many challenges, as reimbursements from federal and state health plans decline. As part of national health reform, hospitals have agreed to give up $155 billion in Medicare reimbursements over 10 years, and we at Mountain States Health Alliance are already feeling the effects of these cutbacks in our operations.

At the same time, many employers in our market have switched to high-deductible benefit plans, which place more responsibility on the patient to use health savings accounts to cover the cost of care. Many of those bills are going unpaid. A large portion of those unpaid bills are balances less than $200, but those balances add up to create a serious obstacle for the health system as we plan for the future. Over the past year, MSHA has experienced a dramatic increase in uncompensated care, which reached $167 million in fiscal 2012. Our charity care alone has nearly doubled in the past 12 months.

As a result, MSHA will now require pre-payment for all elective procedures in the amount of half of the patient's total out-of-pocket expense. **This policy will take effect Sept. 3, 2012 and will apply to qualified procedures that are performed on or after that date.** Patients will be notified of the amount of their obligation prior to admission, and if payment cannot be secured at that time, the elective procedure will be delayed until sufficient payment arrangements can be made. In order to avoid scheduling procedures that will have to be delayed, we are asking referring physicians, when possible, to make patients aware of the hospital's policy before the procedure is scheduled.

This policy has been in place for the uninsured population for several years, but recent reimbursement challenges have made it necessary to apply the policy to the insured population as well. The procedures affected by this policy are determined by diagnosis code and have been fully vetted by the physician leadership of MSHA. Emergent services are unaffected by the policy; MSHA hospitals will continue to perform these procedures regardless of the patient's ability to pay.

(continued)

400 North State of Franklin Road Johnson City, Tennessee 37604-6094 Telephone 423.431.6111

An appeals process will be in place for exceptional cases. If the referring physician wishes to initiate an appeal, he or she may contact the Chief Medical Officer of the facility in question. Thank you for your understanding and cooperation as we work to create an environment that is sustainable, both for patients and providers. If you have questions, feel free to contact one of the MSHA officials listed below.

Sincerely,

Morris H. Seligman, MD, FACP
SVP/Chief Medical Officer,
Mountain States Health Alliance
SeligmanMH@msha.com | 423-302-3373

Frank Lauro, DO, FACC, FACOI
VP/Chief Medical Officer,
Indian Path Medical Center / Mountain States Medical Group
LauroFJ@msha.com | 423-857-7100

Douglas Edema, MD
President/Chief Executive Officer
Mountain States Medical Group
EdemaDA@msha.com | 423-915-5195

Clay Runnels, MD
AVP/Medical Director of Emergency Svcs
Mountain States Health Alliance
RunnelsCW@msha.com | 423-431-1983

Jim Paskert, MD
VP/Chief Medical Officer
MSHA Washington County, TN Operations
PaskertJP@msha.com | 423-431-1061

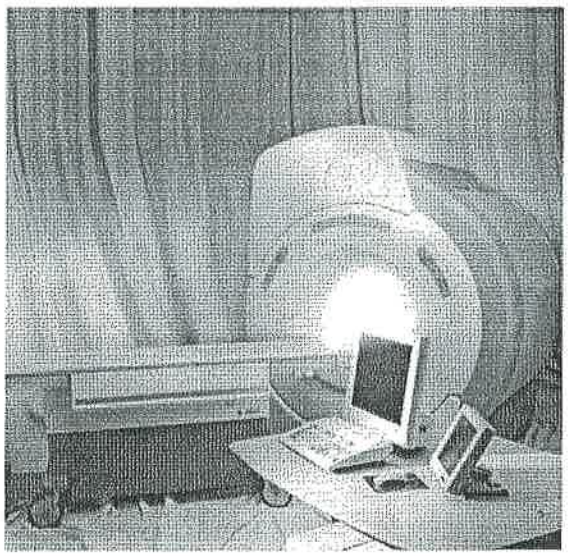
Hughes Melton, MD
VP/Chief Medical Officer,
MSHA Virginia Operations
MeltonSH@msha.com | 276-258-2800

SUPPLEMENTAL - # 1

OiService®

OXFORD INSTRUMENTS
The Business of Science®

Medical Care Imaging, LLC
1500 West Elk Avenue
Elizabethton, TN 37643



Reconditioned GE Signa 1.5T 12x EXCITE 8-Channel MRI Scanner
Equipment Quotation

Prepared By:
Will Hengemuhle, Jr.
March 22, 2013
843.568.9865 Cell

SUPPLEMENTAL - # 1

OiService®

OXFORD INSTRUMENTS

The Business of Science®

AGREEMENT NUMBER: 032213-WH
DATE: March 22, 2013

Reconditioned GE Signa 1.5T 12x Excite 8-Channel MRI

Hardware Summary

- CX-K4 1.5T Actively Shielded Short Bore Magnet
- 1.5T Excite HD EchoSpeed Plus 8-Channel Electronics with Phased Array
- ACGD Plus Gradient Driver 33 mT/m, Slew Rate 120
- Excite Digital RF System
- Detachable Patient Table
- HP Linux Dual Processor Workstation/Operator Console w/ Color LCD Monitor
- Vector 400 Recon Module (Vector 800 available as an option)

Coils

- 8-Channel CTL Spine Array Coil
- 8-Channel Body Coil
- 8-Channel Neurovascular Array
- 4-Channel Torso Array Coil
- 4-Channel Shoulder Array Coil
- Quad Extremity Coil w/ Chimney
- General Purpose Flex Coil (x2)
- Dual TMJ Coil and Dual Array Adaptor
- Breast Coil

12x Software and Options Summary

- EXCITE ScanTools 12x Software
- Spin Echo, Fast Spin Echo
- Gradient Echo, Fast Gradient Echo
- Time of Flight, Phase Contrast
- Echo Planar Pulse Sequence
- FuncTool, ClariView
- ConnectPro (Modality Worklist)
- Performed Procedure Step
- Multi Planar Volume Reformat
- Interactive Vascular Imaging

Advanced Neuro Imaging – EchoPlus, 3D Fiesta, Fiesta—C, Asset

Advanced Body and Breast Imaging – Asset, Firm, Fame, Special, 2D Fat Sat Fiesta, LAVA

Vascular Imaging – SmartPrep, SmartStep, Elliptic Centric, FTMRA

Cardiact Imaging – iDrivePro Plus, FastCine, FastCard, 2D Fiesta, 3D Fat Sat Fiesta

Other Items

- Main Disconnect Panel
- Note: Installation of the above by licensed contractors

****SUBJECT TO AVAILABILITY****

SUPPLEMENTAL - # 1

OiService®

OXFORD INSTRUMENTS 2013 am

The Business of Science®

PURCHASE AND SALE AGREEMENT
(EQUIPMENT)

Oxford Instruments Service LLC ("OI SERVICE"), located at 1027 SW 30th Avenue, Deerfield Beach, FL 33442, hereby agrees to sell; and **Medical Care Imaging, LLC ("PURCHASER"),** located at 1500 West Elk Avenue Elizabethton, TN 37643, hereby agrees to purchase the equipment described below ("Equipment") in accordance with the terms and conditions forth below in this Agreement and the standard terms and conditions set forth in Exhibit A, attached hereto and incorporated to this Agreement by reference:

PURCHASE PRICE: Three Hundred and Ninety-Nine Thousand Dollars, ($399,000.00) ("Purchase Price"). The Purchase Price and any other amounts payable under this Agreement shall be paid in U.S. Dollars by the wire transfer of immediately available funds to bank account directed by OI SERVICE.

EXECUTION OF AGREEMENT AND DEPOSIT BY PURCHASER: PURCHASER shall return an executed Agreement to OI SERVICE on or before November 1, 2013 along with a deposit of $119,700.00 (30% of Purchase Price) via wire transfer of immediately available funds to a bank account directed by OI SERVICE. If PURCHASER fails to execute this Agreement and pay the deposit prior to such date, the terms and conditions set forth in this Agreement shall be null and void.

PAYMENT TERMS: The Purchase Price shall be paid as follows: (i) 30% of the Purchase Price upon the execution of this Agreement; (ii) 60% upon written notice of shipment to PURCHASER's site and prior to delivery of the Equipment to the PURCHASER'S site; and (iii) 10% upon the first use of the Equipment, but no later than 30 days after the delivery of the Equipment.

REFURBISHMENT: Refurbishing of Equipment includes inspecting all mechanical parts and adjusting or replacing parts if necessary, along with professional cleaning and painting to look like new.

LIMITED WARRANTY: The limited warranty provided by OI SERVICE shall be governed pursuant to the terms and conditions set forth on Exhibit "A" attached hereto and made a part hereof.

Every attempt has been made to assure complete and accurate system specifications to the best of our ability.

INSTALLATION, TURNOVER AND ON-SITE APPLICATIONS TRAINING: The installation and turnover of the Equipment, along with applications training shall be governed pursuant to the terms and conditions set forth on Exhibit "A" attached hereto and made a part hereof.

DELIVERY DATE: The Equipment shall be de-installed and delivered on or before December 31, 2013("Delivery Date") at 1500 West Elk Avenue Elizabethton, TN 37643. OI SERVICE shall pay all transportation costs.

SUPPLEMENTAL - # 1

OiService®

OXFORD INSTRUMENTS

The Business of Science®

ACCEPTANCE OF TERMS AND CONDITIONS: OI SERVICE and PURCHASER have carefully read the terms and conditions of this Agreement and its Standard Terms and Conditions. The undersigned are duly authorized to execute this Agreement on behalf PURCHASER and OI SERVICE.

"OI SERVICE"

Oxford Instruments Service LLC

BY: _____
Jeffrey D. Fall

INT:_____
DATE:

"PURCHASER"

Medical Care Imaging, LLC TAX ID No.:

BY: _____
Purchaser Signature

INT:_____
DATE:

EXHIBIT A
STANDARD TERMS AND CONDITION

1. **INCORPORATION OF ADDITIONAL TERMS AND CONDITIONS:** This Exhibit is an integral part of OI SERVICE's offer to sell the Equipment to PURCHASER. By signing the Agreement and the Exhibit and returning it to OI SERVICE, PURCHASER hereby accepts all of the terms and conditions set forth in this Agreement, including, but limited to the terms set forth in this and any other Exhibit.

2. **DEFAULT:**

(a) If OI SERVICE fails to deliver the Equipment within (45) days after the Delivery Date, then PURCHASER shall have the right to cancel this Agreement and receive a full refund of any and all funds paid to OI SERVICE, including, but limited to all deposits and prepayments. The aforementioned refund shall be PURCHASER's sole and exclusive remedy.

(b) If PURCHASER fails to comply with the payment terms described on the first page of this Agreement, and such non-payment continues for a period of five (5) after such payment due date, then in addition to any and all rights and remedies available to OI SERVICE at law or equity, OI SERVICE shall have the right to cancel this Agreement and retain any and all funds paid to OI SERVICE, including, but limited to all deposits and prepayments.

(c) In the event OI SERVICE agrees to accept multiple payments to satisfy the Purchase Price which shall be paid over a period of time, PURCHASER hereby grants OI SERVICE a purchase money security interest under the UCC in all Equipment to secure full payment for such goods is received. PURCHASER shall execute any documents required by OI SERVICE to perfect such security interest in the Equipment, and where permitted PURCHASER hereby authorizes OI SERVICE to sign and file the same without PURCHASER's signature. PURCHASER agrees to pay any and all expenses related to the preparation and filing of such documents.

3. **TRANSFER OF TITLE:** Upon OI SERVICE's' receipt of the full Purchase Price, OI SERVICE shall assign, transfer and convey all of its right, title and interest in the Equipment to PURCHASER, free and clear of all liens and encumbrances.

4. **INSTALLATION, TURNOVER AND ON-SITE APPLICATIONS TRAINING:**

(a) OI SERVICE shall provide PURCHASER with site planning assistance including preliminary/final room drawings. OI SERVICE shall only perform commercially normal installation. There will be no special rigging requirements such as the use of cranes. The PURCHASER agrees to pay upon receipt of invoice from OI SERVICE any amount above $7,500 for rigging of the Equipment into the site of installation.

(b) PURCHASER shall be responsible to prepare the site in accordance with the site plan and the specifications of the Original Equipment Manufacturer (OEM). All applicable, licenses and/or permits shall be the responsibility of the PURCHASER.

(c) OI SERVICE shall provide 7-days on-site applications training. The training schedule is generally 4-5 days following the turnover of the Equipment, and 2-3 days follow up. Training is approved for CEU's.

(d) The following Service shall not be provided by OI SERVICE:

(i) RF Room and Shielding

(ii) Installation of air conditioning units, water chillers, and electrical panels and related equipment and environmental which shall be performed by licensed contractors hired by PURCHASER.

(iii) Site modifications and renovations to the installation site as would be required by Original Equipment Manufacturer (OEM) specifications.

(e) The procedure for the installation and turnover of the Equipment, along with on-site applications training is as follow:

(i) Upon the delivery of the Equipment and upon PURCHASER's completion of site preparation, OI SERVICE shall commence installation the Equipment (in accordance with the provision set forth in paragraphs (a) and (b) above); provided that if Purchaser delays the installation of the Equipment or the site has not been properly prepared by Purchaser for installation within 5 business days of the Delivery Date, then the installation and turnover of the Equipment shall be deemed accepted. Further, shall pay OI SERVICE a storage fee in the amount of $2,000.00 per month (plus the cost of any cryogens required to keep the magnet cold while in storage), and such fees shall be due and payable prior to the delivery and installation of the Equipment at the site.

(ii) OI SERVICE shall schedule and provide Purchaser's employees with application training for the Equipment(in accordance with the provision set forth in paragraph (c) above) upon completion of the installation of the Equipment; provided however, if Purchaser delays the application training by more than 5 business days, then the installation and turnover of the Equipment shall be deemed accepted.

(iii) Upon completion of the installation of the Equipment and the applications training, OI SERVICE shall provide Purchaser with a Certificate of Acceptance which shall provide that: (A) the Equipment has been properly installed and the Equipment meets or exceeds the original specifications of the original equipment manufacturer, and (B) the application training has been completed.

(iv) Purchaser shall have 5 business days from the receipt of the Certificate of Acceptance to provide OI SERVICE with either: (A) written acceptance to the installation and turnover of the Equipment; or (B) provide OI SERVICE with written notice which describes any issues relating to the Equipment's conditions or specifications, the installation of the Equipment or the application training.

(v) If Purchaser fails to provide OI SERVICE with a written response to the Certificate of Acceptance in accordance with subparagraph (iv) above, then the installation and turnover of the Equipment shall be deemed accepted.

5. **RISK OF LOSS:** The risk of loss from any damages or casualty to the Equipment shall passes from OI SERVICE to PURCHASER when the Equipment is duly delivered to the transportation carrier or the Equipment is picked up by the transportation carrier.

6. **LIMITED WARRANTY**:

(a) Subject to the provisions set forth below, OI SERVICE shall provide a limited warranty for a 12 month period commencing on the earlier of: (i) acceptance of the Equipment by PURCHASER (in accordance with the terms set forth on Exhibit "A"), or (ii) first clinical use and billing of patient ("Warranty Period"). The warranty coverage period is M-F, 8am—5pm, excluding holidays.

(b) OI SERVICE warrants that the Equipment is free from defects in material or workmanship under normal use and service. There shall be no warranty on consumables. The limited warranty shall cover all parts and labor (surface coils and cryogens – which shall not exceed 1000 liters).

(c) Any Equipment found to be defective during the "Warranty Period shall be repaired or replaced free of charge, provided that PURCHASER satisfies all of the following conditions: (i) PURCHASER gives written notice of the defect (with reasonable relevant information) to OI SERVICE as soon as reasonably practicable and within the Warranty Period; (ii) the Equipment has been used solely for its proper purpose and in accordance with the operating instructions specified by the original equipment manufacturer (including, but not limited to meet or exceed the proper power requirements in accordance with the specifications of the original equipment manufacturer and all HVAC requirements); (iii) the defect has not been caused by fire, accident, misuse, neglect, incorrect installation by PURCHASER or its customers, agents or servants, (iv) there has been no unauthorized alteration, repair or maintenance or the use of sub-standard consumables; (v) the defect has not arisen from any design, specification, component or material supplied by or on behalf of PURCHASER; (vi) no part of the Equipment has been replaced with a part not supplied or

approved by OI SERVICE; ((vii) all repairs to the Equipment have been made by personal of OI SERVICE or approved by OI SERVICE; (viii) PURCHASER has made all payments due and owing to OI SERVICE.

In the event PURCHASER fails to meet the requirements set forth in sub-paragraph (c)(ii) above, OI SERVICE shall have the right to impose additional charges to PURCHASER or void the limited warranty set forth herein, as provided by OI SERVICE in its sole discretion.

(d) PURCHASER shall be liable for any costs incurred by OI SERVICE in responding to claims caused by operator error or incorrect application or other default of PURCHASER or other third party;

(e) PURCHASER shall pay the costs of all consumables.

(f) OI SERVICE, at its sole discretion, shall determine whether to replace or repair the Equipment.

(g) If a part fails within this Warranty Period and is replaced or repaired, then the new part will have a warranty period equal to the remaining period of the part that failed.

(h) OI SERVICE, at is option and sole discretion, may repair the Equipment at the site of PURCHASER or direct PURCHASER to have the Equipment returned to OI SERVICE's premises. If repairs are made at the location of PURCHASER, OI SERVICE will not charge for the cost of materials or labor but will, at its discretion, charge travelling and subsistence expenses incurred by OI SERVICE's representatives; and

(i) PURCHASER shall accord OI SERVICE and its representatives or agents sufficient and timely access to the Equipment to enable its staff to inspect and adjust, repair, remove or replace the agents sufficient and timely access to the Equipment to enable its staff to inspect and adjust, repair, remove or replace the Equipment; and

(j) THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, DESCRIPTION AND FITNESS FOR PARTICULAR PURPOSE.

7. LIMITATION OF WARRANTIES AND LIABILITY, HOLD HARMLESS:

(a) PURCHASER ACKNOWLEDGES THAT OI SERVICE DID NOT MANUFACTURE THE EQUIPMENT, AND THAT EXCEPT AS SET FORTH HEREIN, OI SERVICE MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE, WITH RESPECT TO THE EQUIPMENT. THIS AGREEMENT STATES OI SERVICE'S ENTIRE OBLIGATION WITH RESPECT TO THIS TRANSACTION. EXCEPT AS SET FORTH HERIN, OI SERVICE PROVIDES NO WARRANTY OF OPERABILITY AND WILL HAVE NO LIABILITY FOR ANY FAILURE OF THE EQUIPMENT AFTER PURCHASER OR ITS AGENTS TAKE TITLE AND BEGIN DEINSTALLATION. IN NO EVENT WILL OI SERVICEOR ITS AGENTS BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES, INCLUDING LOSS OF USE, PROJECTED PROFITS, OR OTHER FINANCIAL LOSSES DERIVING FROM THE SALE OR USE OF THE ABOVE MENTIONED EQUIPMENT, NOR SHALL OI SERVICEOR ITS AGENTS BE LIABLE FOR ANY DAMAGES FOR BODILY INJURY.

(b) PURCHASER AGREES TO INDEMNIFY, DEFEND, AND HOLD HARMLESS OI SERVICE AGAINST ANY AND ALL CLAIMS JUDGMENTS, COSTS (INCLUDING ACTUAL ATTORNEY FEES), EXPENSES, OR OTHER LOSSES TO ANY PERSON, GROUP OR ENTITY, DERIVING FROM OI SERVICE'S SERVICE. IN THE EVENT THAT THE TRANSFER IS NOT COMPLETED FOR ANY REASON, INCLUDING FORCE MAJEURE, ACTS OF WAR OR GOD, OR WITHDRAWAL OF THE EQUIPMENT FOR SALE, THE SOLE LIABILITY OF OI SERVICE SHALL BE LIMITED TO THE RETURN OF ALL MONIES ALREADY PAID TO OI SERVICE BY PURCHASER, INCLUDING DEPOSITS. PURCHASER WILL HAVE NO

OTHER REMEDY UNDER LAW FOR ANY REASON WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOSS OF USE OR DERIVATIVE PROFITS OR ANY OTHER DAMAGES.

8. **SOFTWARE.**

(a) PURCHASER acknowledges and agrees that OI SERVICE has no rights, titles, and interest in and to software relating to the Equipment, and that OI SERVICE has no right to grant any licenses thereunder. PURCHASER further acknowledges and agrees that all, rights, title and interest in such software remains with the original equipment manufacturer ("OEM").

(b) OI SERVICE make no representations and warranties to PURCHASER that the software was properly installed in the Equipment and that it will perform substantially as described in the OEM's specification for the Equipment.

(c) By executing this Agreement, the PURHASER hereby designates OI SERVICE as PURCHASER's attorney in fact, with full power and authority to act on PURCHASER's behalf with the OEM in connection with obtaining the necessary software from the OEM to operate, repair or maintain the Equipment.

9. **TAXES:** Any sales, use, property, or other taxes or regulatory fees applicable to this transaction will be in addition to the purchase price quoted, and shall be due and payable by PURCHASER. PURCHASER shall provide to OI SERVICE proof of any claimed exemption from the foregoing items.

10. **SUBCONTRACTORS:** OI SERVICE reserves the right to utilize sub-contracts for any of the required to meet its obligations under this Agreement.

11. **APPLICABLE LAW, ARBITRATION, LITIGATION, JURISDICTION, AND VENUE:**

(a) This Agreement shall be governed by and interpreted by the laws of the State of Massachusetts. Any Controversy or Claim arising out of or in relation to this Agreement, or breach thereof, shall be submitted to binding arbitration. Any such arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association, but not necessarily administered by the American Arbitration Association. The venue of any such arbitration shall be the State of Massachusetts. Any controversy will be submitted to a panel of three arbitrators. PURCHASER and OI SERVICE shall each select one arbitrator and those arbitrators shall select a third arbitrator. Any arbitrator must be a member of the Massachusetts Bar Association. The fees for the arbitrators will be levied as follows: PURCHASER and OI SERVICE will each be responsible for paying the respective fee of the arbitrator they selected. PURCHASER and OI SERVICE will each pay fifty percent (50%) of fees charged by the third arbitrator. Judgment upon the award rendered by the arbitrators may be entered and enforced by any court having jurisdiction. The prevailing party in arbitration shall be awarded all costs incurred in connection with the pursuit of its claims, including filing fees, arbitrators' fees, and reasonable attorney fees.

(b) PURCHASER hereby consents to personal jurisdiction in the State of Massachusetts and to venue in the county or federal district in which OI SERVICE maintains its headquarters.

12. **ENTIRE AGREEMENT, NON-CANCELLATION:** This Agreement (and all exhibits) represents the entire agreement between the parties, is a final expression of that agreement, is non-cancelable, and supersedes any previous oral or written agreements between the parties. Any changes must be in writing signed by both parties. This Agreement will not be binding until signed by both parties, and can be withdrawn by either party at any time, without notice, prior to signature by either party.

13. **MISCELLANEOUS PROVISIONS:**

(a) Paragraph headings used in this Agreement are of no legal effect;

(b) If any provision contained in this Agreement is determined to be invalid, illegal or otherwise unenforceable, the remaining provisions shall be fully enforceable;

(c) Any forbearance by either party from enforcing any term of this Agreement shall not constitute a waiver of any right under this Agreement, unless stated in writing;

(d) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. A copy of a signature received through telefax transmission or other electronic means (including in Adobe pdf or similar format) shall bind the party whose signature is so received as if such signature were an original;

(e) PURCHASER may not assign any of its rights or obligations under this Agreement without the prior written consent of OI SERVICE which consent shall not be unreasonably withheld;

(f) All Exhibits to this Agreement are expressly made a part of this Agreement as fully as though completely set forth in this Agreement;

OI SERVICE and PURCHASER do each hereby agree and accept the terms and conditions set forth in this Exhibit.

"OI SERVICE"

Oxford Instruments Service LLC

BY: _____
Jeffrey D. Fall

INT: _____

DATE:

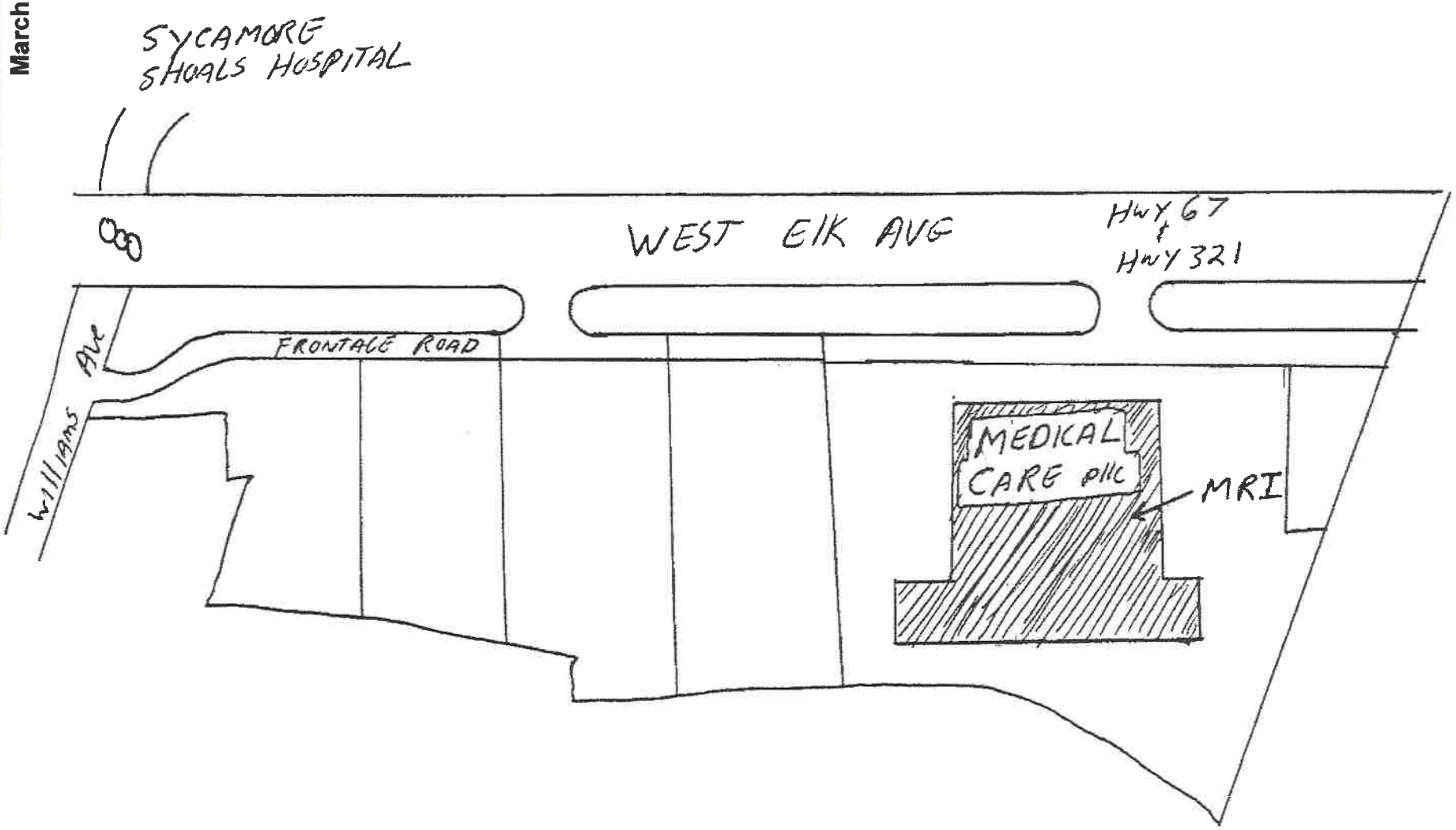
"PURCHASER"

Medical Care Imaging, LLC TAX ID No.:

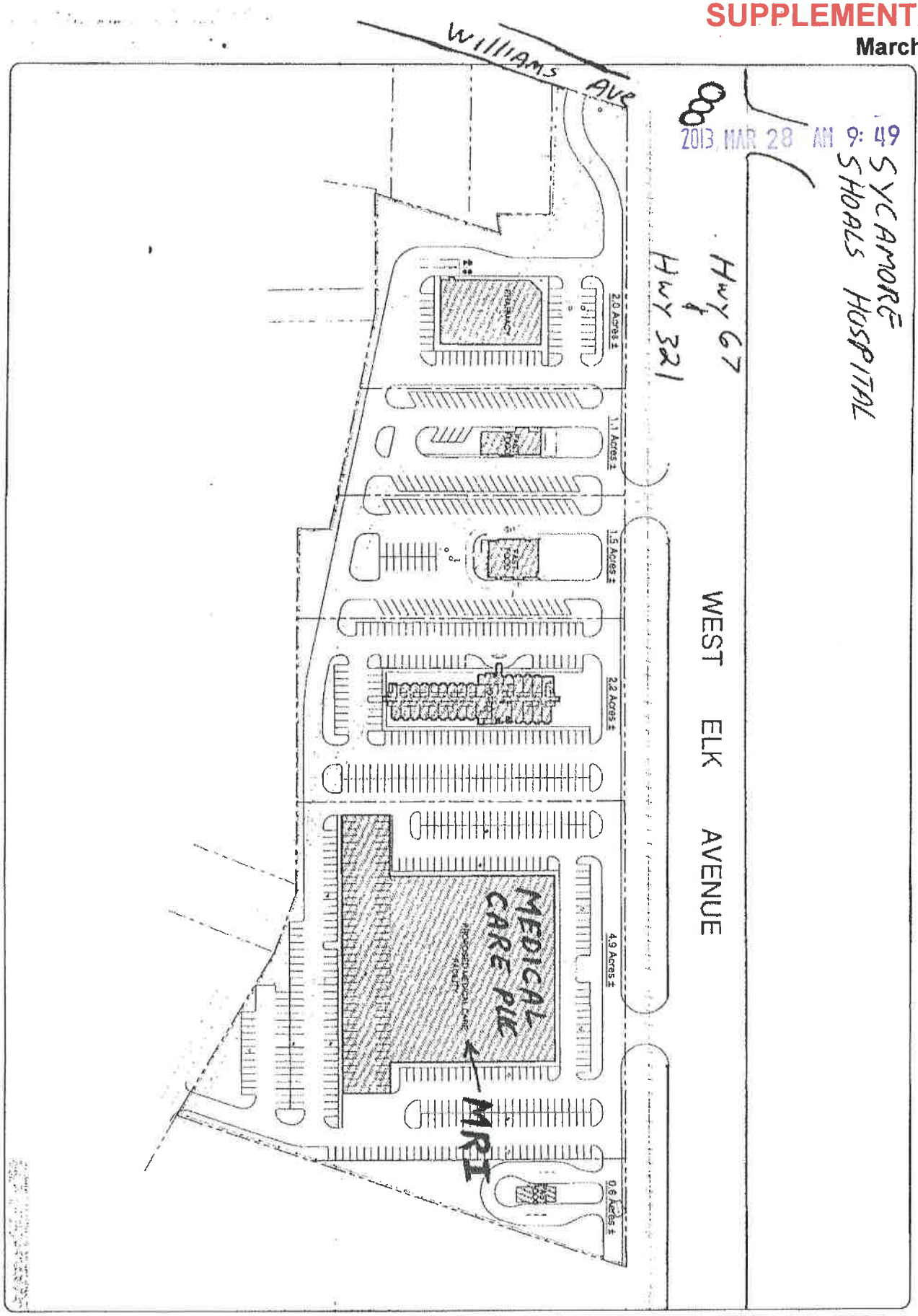
BY: _____
Purchaser Signature

INT: _____

DATE:



SUPPLEMENTAL- # 1
March 28, 2013
9:46 am



P4

DEVELOPMENT PLANS FOR
MEDICAL CARE
ELIZABETHTON, TENNESSEE

PRELIMINARY MASTER PLAN
LAYOUT 4

Benchmark Design, PLC

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

Medically Underserved Areas / Populations (MUA/P)

1. Select Format 2. Filter Results 3. Sort By 4. Columns 5. Summarize 6. Review

Run Report | Start Over | Help

User Instructions: "Filter Results" controls the scope of data included in your report. Use the "... Read More

Available Filters (optional)

County, State

Please make one or more selections from the available County, State data in the list box below and click the Add button. [How to select/de-select multiple values?]

Autauga County, AL
Baldwin County, AL
Barbour County, AL
Bibb County, AL
Blount County, AL
Bullock County, AL
Butler County, AL
Calhoun County, AL
Chambers County, AL
Cherokee County, AL
Chilton County, AL
Choctaw County, AL
Clarke County, AL
Clay County, AL
Cleburne County, AL
Coffee County, AL
Colbert County, AL
Conecuh County, AL
Coosa County, AL
Covington County, AL
Crenshaw County, AL
Cullman County, AL
Dale County, AL
Dallas County, AL
DeKalb County, AL
Elmore County, AL
Escambia County, AL
Etowah County, AL
Fayette County, AL
Franklin County, AL
Geneva County, AL
Greene County, AL
Hale County, AL
Henry County, AL
Houston County, AL
Jackson County, AL
Jefferson County, AL
Lamar County, AL
Lauderdale County, AL
Lawrence County, AL
Lee County, AL
Limestone County, AL
Lowndes County, AL
Macon County, AL
Madison County, AL
Marengo County, AL
Marion County, AL
Marshall County, AL
Mobile County, AL
Monroe County, AL
Montgomery County, AL
Morgan County, AL
Perry County, AL
Pickens County, AL
Pike County, AL
Randolph County, AL
Russell County, AL
Shelby County, AL
St. Clair County, AL
Sumter County, AL
Talladega County, AL
Tallapoosa County, AL
Tuscaloosa County, AL
Walker County, AL
Washington County, AL
Wilcox County, AL
Winston County, AL
Aleutians East Borough, AK
Aleutians West Census Area, AK
Anchorage Borough, AK
Bethel Census Area, AK
Bristol Bay Borough, AK

Add

Selected Filters
County, State
- Carter County, TN
- Johnson County, TN
- Unicoi County, TN
- Washington County, TN

Remove

Previous | Run Report | Next

Total Records: 6 Export to Excel Page Top

County, State	Designation Type	HHS Region	IMU Score	Last Activity Date	MCD Code	MCD Name	MUA/P Designation Date String	MUA/P ID	MUA/P Service Area	MUA/P Status Code	MUA/P Update Date String	Primary Region	Primary Region Code	Primary State	Primary State Abbreviation	Primary State FIPS Code	Service Area Name	Service Area Type
Carter County, TN	Medically Underserved Area	Region IV	55.20	1978/11/01			1978/11/01	03179	47019	D		Region IV	04	Tennessee	TN	47	Carter Service Area	Whole County
Johnson County, TN	Medically Underserved Area	Region IV	51.50	1978/11/01			1978/11/01	03204	47091	D		Region IV	04	Tennessee	TN	47	Johnson Service Area	Whole County
Unicoi County, TN	Medically Underserved Area	Region IV	59.30	2012/05/14			1978/11/01	03234	47171	D	2012/05/14	Region IV	04	Tennessee	TN	47	Unicoi County	Whole County
Washington County, TN	Medically Underserved Area	Region IV	42.20	1994/05/12	4717990940	District 5	1994/05/12	03268	4717990940	D		Region IV	04	Tennessee	TN	47	Bethesda Division Service Area	Partial County
Washington County, TN	Medically Underserved Area	Region IV	42.20	1994/05/12	4717991510	District 6	1994/05/12	03268	4717991510	D		Region IV	04	Tennessee	TN	47	Bethesda Division Service Area	Partial County
Washington County, TN	Medically Underserved Area	Region IV	42.20	1994/05/12	4717991700	District 9	1994/05/12	03268	4717991700	D		Region IV	04	Tennessee	TN	47	Bethesda Division Service Area	Partial County

SUPPLEMENTAL- # 1

March 28, 2013

9:46 am

Find Shortage Areas: MUA/P by State and County

Shortage Designation Home

Find Shortage Areas

HPSA & MUA/P by Address

HPSA by State & County

HPSA Eligible for the Medicare Physician Bonus Payment

Criteria:

State: Tennessee
County: Carter County
Johnson County
Unicoi County
Washington County
ID #: All

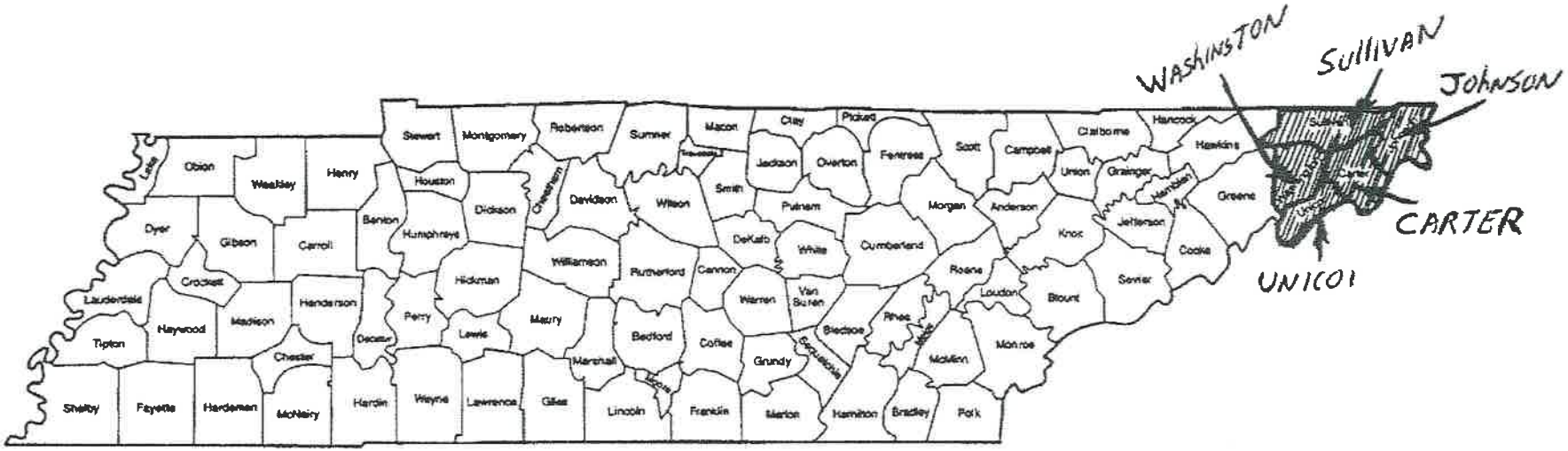
Results: 7 records found.

Name	ID#	Type	Score	Designation Date	Update Date
Carter County					
Carter Service Area	03179	MUA	55.20	1978/11/01	
MCD (?) Unknown					
Johnson County					
Johnson Service Area	03204	MUA	51.50	1978/11/01	
MCD (?) Unknown					
Unicoi County					
Unicoi County	03234	MUA	59.30	1978/11/01	2012/05/14
MCD (?) Unknown					
Washington County					
Bethesda Division Service Area	03268	MUA	42.20	1994/05/12	

NEW SEARCH | MODIFY SEARCH CRITERIA

Medical Care, PLLC

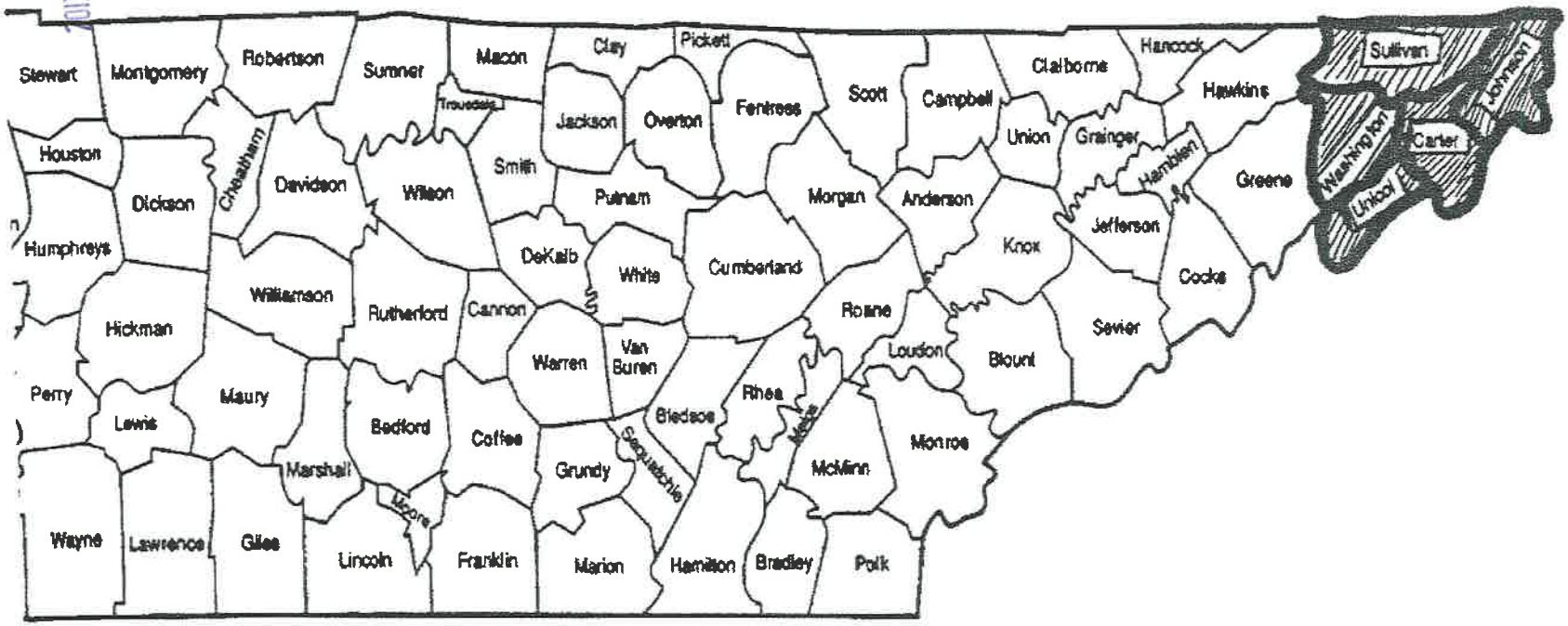
Proposed MRI Service area



Proposed service area includes; Carter, Johnson, Unicoi, Sullivan, and Washington counties in Tennessee

Medical Care, PLLC

Proposed MRI Service Area



Proposed Service Areas includes; Carter, Johnson, Unicoi, Sullivan, and Washington Counties

P.O. Box 940
Johnson City, TN 37605-0940

State of Franklin BANK
A division of Jefferson Federal Bank

P.O. Box 208
Kingsport, TN 37662-0208

March 26, 2013

Mr. Steve Hopland
Medical Care PLLC
1500 West Elk Avenue
Elizabethton, TN 37643

Dear Mr. Hopland:

State of Franklin Bank, a division of Jefferson Federal Bank, is pleased to offer you the following proposals to finance the purchase of a G.E. 1.5T MRI, as further described in Contract of Sale #092212A from M.E.D. Inc and a GE Signa 1.5T Excite 8-Channel MRI described in Agreement Number 121712-WH from Oxford Instruments, along with related attachments/expenses associated with the installation. The proposal is subject to the satisfactory review of all financial information on the borrower(s) and conditions to meet the bank's lending policy and/or state and federal guidelines and should not be construed to be final approval.

Loan Amount:	$839,000
Interest Rate:	5.00%
Amortization:	For a period not to exceed 60 months.
Origination Fee:	None.
Repayment Terms:	The fixed monthly principal and interest payments based on an amortization period not to exceed 60 months.
Loan to Value:	N/A
Collateral:	Equipment to be purchased along with all attachments.
Guarantors:	Dr. Arnold Hopland, Dr. Jeffery Hopland, Dr. Kenneth Hopland, Steve Hopland and Jennifer Whaley, along with all spouses.
Environmental Assessment:	N/A
Insurance:	A mortgage policy naming State of Franklin Bank, a division of Jefferson Federal Bank, as mortgagee shall be required at closing.

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

Closing Cost:	The borrower shall be responsible for all closing costs associated with this loan including but not limited to attorney fees, appraisal fees, environmental assessments or any other cost. If the loan does not close, any fees generated will be paid by the borrower upon request by the bank.
Prepayment:	No prepayment fee will be assessed.
Other terms & Conditions:	A Balance Sheet and Income Statement, along with prior year tax returns, shall be delivered to the bank on a timely basis after the fiscal year on all borrowers or anytime the bank deems necessary.

The Directors, Officers and staff are pleased you have given the bank the opportunity to review your request. If you have any questions please feel free to call.

Sincerely,

Harvey L. Mitchell
President, Tri-Cities Division

Acceptance of these terms and conditions are required by April 15, 2013 and if approved closed by May 15, 2013. Any changes to these terms and condition shall be in writing and approved by State of Franklin Bank.

Accepted:

BY_____ _____ _____
Title Date

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2010	Year 2011	Year 2012
A. Utilization Data (Specify unit of measure) CPT's	233,492	260,351	254,696
B. Revenue from Services to Patients			
1. Inpatient Services	$ -	$ -	$ -
2. Outpatient Services	$15,349,854	$17,411,255	$18,228,256
3. Emergency Services	-	-	-
4. Other Operating Revenue (Specify)_____	-	-	-
Gross Operating Revenue	$15,349,854	$17,411,255	$18,228,256
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	$6,769,519	$7,612,200	$8,403,226
2. Provision for Charity Care	920,991	748,684	747,358
3. Provisions for Bad Debt	461,927	554,347	1,044,229
Total Deductions	$8,152,437	$8,915,231	$10,194,813
NET OPERATING REVENUE	$7,197,417	$8,496,024	$ 8,033,443
D. Operating Expenses			
1. Salaries and Wages	$1,875,470	$2,155,904	$2,290,216
2. Physician's Salaries and Wages	$2,080,586	$2,054,709	$2,106,806
3. Supplies	$ 174,800	$ 213,389	$ 260,316
4. Taxes	$ 303,499	$ 354,482	$ 249,982
5. Depreciation	$ 376,472	$ 384,042	$ 195,462
6. Rent			
7. Interest, other than Capital			
8. Management Fees:			
a. Fees to Affiliates	$2,357,923	$2,393,264	$2,624,563
b. Fees to Non-Affiliates			
9. Other Expenses – Specify on Page 23			
Total Operating Expenses	$7,168,750	$7,555,790	$7,727,345
E. Other Revenue (Expenses) – Net (Specify)_____	$	$	$
NET OPERATING INCOME (LOSS)	$ 28,667	$ 940,234	$ 306,098
F. Capital Expenditures			
1. Retirement of Principal	$(1,462,695)	$(506,331)	$(4,404,830)
2. Interest	149,922	247,016	351,847
Total Capital Expenditures	$(1,312,773)	$(259,315)	$(4,052,983)
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	$ 1,341,440	$ 1,199,549	$ 4,359,081

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 1	Year 2
A.	Utilization Data (Specify unit of measure)	2,756	2,894
B.	Revenue from Services to Patients		
1.	Inpatient Services	$ -	$ -
2.	Outpatient Services	$4,369,776	$4,588,582
3.	Emergency Services	-	-
4.	Other Operating Revenue (Specify)_____	-	-
	Gross Operating Revenue	$ 4,369,776	$ 4,588,582
C.	Deductions from Gross Operating Revenue		
1.	Contractual Adjustments	$ 1,909,591	$ 2,005,210
2.	Provision for Charity Care	$ 218,489	$ 229,429
3.	Provisions for Bad Debt	$ 131,093	$ 137,657
	Total Deductions	$ 2,259,173	$ 2,372,296
NET OPERATING REVENUE		$ 2,110,603	$ 2,216,286
D.	Operating Expenses		
1.	Salaries and Wages	$ 282,800	$ 318,500
2.	Physician's Salaries and Wages	$ 206,700	$ 217,050
3.	Supplies	$ 275,600	$ 289,400
4.	Taxes	-	-
5.	Depreciation	$ 75,000	$ 75,000
6.	Rent	$ 23,590	$ 23,590
7.	Interest, other than Capital	-	-
8.	Management Fees:		
	a. Fees to Affiliates	$ 316,590	$ 332,443
	b. Fees to Non-Affiliates	-	-
9.	Other Expenses – Specify on Page 23	$ 150,000	$ 150,000
	Total Operating Expenses	$ 1,330,280	$ 1,405,983
E.	Other Revenue (Expenses) -- Net (Specify)_____	$ -	$ -
NET OPERATING INCOME (LOSS)		$ 780,323	$ 810,303
F.	Capital Expenditures		
1.	Retirement of Principal	$ 94,792	$ 99,641
2.	Interest	$ 24,097	$ 19,248
	Total Capital Expenditures	$ 118,889	$ 118,889
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$ 661,434	$ 691,414

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

8:30 AM
03/25/13
Cash Basis

Medical Care PLLC
Balance Sheet
As of December 31, 2012

	Dec 31, 12
ASSETS	
Current Assets	
Checking/Savings	
1000-00 · State of Franklin	101,027.26
Total Checking/Savings	101,027.26
Total Current Assets	101,027.26
TOTAL ASSETS	101,027.26
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	
2100-00 · Payroll Liabilities	-956.56
2130-00 · Due to Pine Palms Mgmt	101,112.51
Total Other Current Liabilities	100,155.95
Total Current Liabilities	100,155.95
Total Liabilities	100,155.95
Equity	
3900-00 · Retained Earnings	667.71
Net Income	203.60
Total Equity	871.31
TOTAL LIABILITIES & EQUITY	101,027.26

SUPPLEMENTAL- # 1
March 28, 2013
9:46 am

8:30 AM
03/25/13
Cash Basis

Medical Care PLLC
Profit & Loss
January through December 2012

	Jan - Dec 12
Ordinary Income/Expense	
Income	
4005-00 · Deposit/daily	7,244,027.48
4015-00 · Pharmacy	788,329.47
4550-00 · Refund	3.00
4560-00 · Returned Checks	-1,161.24
4910-00 · Rebate Income	2,245.10
4975-00 · Bank Errors	-0.30
Total Income	8,033,443.51
Gross Profit	8,033,443.51
Expense	
5500-00 · Payroll Expenses	
5501-00 · Wages -Hourly	24,317.20
5512-00 · Salaries to PA's	85,603.24
5514-00 · Salaries to FNP's	634,207.92
5520-00 · Salaries To MD's	578,267.66
5600-01 · Payments to Officer #1-AH	147,844.82
5600-02 · Payments to Officer #2-JH	237,803.92
5600-04 · Payments to Officer #4-KH	249,776.13
5500-00 · Payroll Expenses - Other	136,992.56
Total 5500-00 · Payroll Expenses	2,094,813.45
5522-00 · Net Paychecks	9,993.13
5750-00 · Bank Service Charges	3,222.31
6020-00 · Employee Benefits	
6028-00 · Others	2,000.00
Total 6020-00 · Employee Benefits	2,000.00
6180-00 · Insurance	
6420-00 · Work Comp	5,321.80
Total 6180-00 · Insurance	5,321.80
6240-00 · Miscellaneous	50.00
6640-00 · Managerial Services	5,830,624.43
6645-00 · Professional Fees	2,438.58
6672-00 · Office Expenses	150.00
6820-00 · Taxes	
6830-00 · Payroll Taxes	84,626.21
6860-00 · Franchise and Excise Taxes	100.00
Total 6820-00 · Taxes	84,726.21
Total Expense	8,033,339.91
Net Ordinary Income	103.60
Other Income/Expense	
Other Expense	
8010-00 · Other Expenses	-100.00
Total Other Expense	-100.00
Net Other Income	100.00
Net Income	203.60

STATE OF TENNESSEE
COUNTY OF CARTER

2013 MAR 2

Judy C. Guinn OF SAID COUNTY BEING DULY SWORN, DEPOSETH AND SAITH THAT SHE IS THE ASSISTANT TREASURER OF THE ELIZABETHTON STAR, A NEWSPAPER PUBLISHED AT ELIZABETHTON IN THE COUNTY OF CARTER, STATE OF TENNESSEE, AND THE ORDER AND NOTICE, OF WHICH IS ANNEXED IS A TRUE COPY, WHICH WAS PUBLISHED IN SAID PAPER FOR One-Day ~~CONSECUTIVE WEEKS,~~

~~COMMENCING~~ ON THE 8th DAY OF Mar., 2013
~~AND ENDING~~ ON THE 8th DAY OF Mar., 2013

Sworn to and subscribed before me this
the 8th day of Mar., 2013

Judy C. Guinn

Nathan C. Goodwin

NOTARY PUBLIC

My commission expires *November 19, 2014*

NATHAN C. GOODWIN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF CARTER

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

March 28, 2013
9:46 am

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 66-1601 *et seq.*, and the Rules of the Health Services and Development Agency that Medical Care, PLLC, professional private practice, owned by: Medical Care, PLLC with an ownership type of professional limited liability company and to be managed by: Pine Palms Management, LLC intends to file an application for a Certificate of Need for initiation of magnetic resonance imaging (MRI) services to its patients at 1500 West Elk Avenue in Elizabethton, Carter County, Tennessee. The project costs are $838,543. The project does not include the acquisition of major medical equipment, will not require facility licensure and affects no licensed inpatient bed complements.

The anticipated date of filing the application is: March 8, 2013. The contact person for this project is Rachel C. Nelley, Esq., Attorney, who may be reached at Nelley & Company, PLLC, P.O. Box 150731, Nashville, TN 37215, (615) 274-4839.

Upon written request by interested parties, a local Fact-Finding hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
The Frost Building, Third Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Tennessee Health Services &
Development Agency
Attn: Rachel C. Nelley
Certificate-of-Need
Published: March 8, 2013
Cost: $204.00

Copy

Supplemental #2

Medical Care, PLLC

CN1303-006

nelley & company plic

Rachel C. Nelley, Attorney
rachel@nelleycompany.com
615.274.4838

April 8, 2013

VIA HAND DELIVERY

Mr. Phillip M. Earhart
Health Services Examiner
TN Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, TN 37243

Re: Certificate of Need Application CN1303-006
Medical Care, PLLC

Dear Mr. Earhart:

This letter will serve to follow up the filing of the above-referenced certificate of need application and is submitted as a second supplemental response to your e-mail correspondence dated April 1, 2013, wherein additional information or clarification was requested.

1. **Section C. Economic Feasibility Item 4**

   Please specify other expenses in the Projected Data Chart listed in D. Operating Expenses 9. Other Expenses. Also, please remove reference to page 23. If needed, a blank Projected Data Chart is enclosed.

   Response: *A revised Projected Data Chart is enclosed.*

2. **Section C. Economic Feasibility Item 5**

   Please recalculate the average deduction from operating revenue and average net charge on page 36 and resubmit a replacement page. Please include contractual deductions in your calculation.

   Response: *The requested replacement page 36 is enclosed.*

3. **Section C. Economic Feasibility Item 6.A**

The table for average gross chart, average projected deduction, average projected net charges, etc. on page 36 of the application is noted. The figures appear to not match the projected data chart totals. Please recheck and include the changes on the same replacement page as referenced in the previous question.

Response: *The enclosed replacement page 36 includes the revised table for average gross charge, average projected deduction, average projected net charge, anticipated gross operating revenue and anticipated net operating revenue set forth below:*

	Year 1	Year 2
Average Gross Charge	$1584.55	$1584.55
Average Projected Deduction	$691.89	$691.89
Average Projected Net Charge	$892.66	$892.66
Anticipated Gross Operating Revenue	$4,367,020	$4,585,688
Anticipated Net Operating Revenue	$2,460,171	$2,583,358

4. **Section C. Economic Feasibility Item 8**

The applicant documents project financial viability on page 39 by stating net operating income less capital expenditures is projected to be $978,024 in Year One and $1,023,856 In Year 2 in the Projected Chart. These totals do not match figures in the supplemental Projected Data Chart that includes management fees of $661,434 in Year One and $691,414 in Year Two. Please correct and submit a replacement page 39.

Response: *The requested replacement page 39 is enclosed and indicates that net operating income less capital expenditures is projected to be $773,783 in year 1 and $807,140 in year 2.*

5. Section C. Orderly Development, Item 8 and 9

The applicant responded to items 8 and 9 of the Economic Feasibility section rather than the requested items of items 8 and 9 in the Orderly Development section on page 44 of the application. Please provide a response.

Response: *The requested responses are set forth below:*

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Response: *No such final orders or judgments exist.*

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Response: *No such final or judgments exist.*

Should you have any questions or require additional information pertaining to this application, please do not hesitate to contact me by telephone at 615.274.4838 or by e-mail at rachel@nelleycompany.com.

Very truly yours,

Rachel C. Nelley
Attorney

Attachments
cc: Steve Hopland, Medical Care, PLLC

SUPPLEMENTAL- # 2
April 8, 2013
12:05 pm

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in **January** (Month).

2013 APR 8 PM 12 06

		Year 1	Year 2
A.	Utilization Data (Specify unit of measure) MRI Studies	2756	2894
B.	Revenue from Services to Patients		
1.	Inpatient Services	$ -	$ -
2.	Outpatient Services	$ 4,367,020	$ 4,585,688
3.	Emergency Services	-	-
4.	Other Operating Revenue (Specify)_____		
	Gross Operating Revenue	$ 4,367,020	$ 4,585,688
C.	Deductions from Gross Operating Revenue		
1.	Contractual Adjustments	$ 1,754,304	$ 1,842,147
2.	Provision for Charity Care	$ 57,187	$ 60,051
3.	Provisions for Bad Debt	$ 95,358	$ 100,132
	Total Deductions	$ 1,906,849	$ 2,002,330
NET OPERATING REVENUE		$ 2,460,171	$ 2,583,358
D.	Operating Expenses		
1.	Salaries and Wages	$ 282,800	$ 318,500
2.	Physician's Salaries and Wages	$ 206,700	$ 217,050
3.	Supplies	$ 275,600	$ 289,400
4.	Taxes	-	-
5.	Depreciation	$ 75,000	$ 75,000
6.	Rent	$ 23,590	$ 23,590
7.	Interest, other than Capital	-	-
8.	Management Fees:		
	a. Fees to Affiliates	$ 661,434	$ 691,414
	b. Fees to Non-Affiliates		
9.	Other Expenses – Specify	$ 108,000	$ 108,000
	Total Operating Expenses	$ 1,633,124	$ 1,722,954
E.	Other Revenue (Expenses) -- Net (Specify)_____	$	$
NET OPERATING INCOME (LOSS)		$ 827,047	$ 860,404
F.	Capital Expenditures		
1.	Retirement of Principal	$ 22,311	$ 23,687
2.	Interest	$ 30,953	$ 29,577
	Total Capital Expenditures	$ 53,264	$ 53,264
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$ 773,783	$ 807,140

SUPPLEMENTAL- # 2
April 8, 2013
12:05 pm

2013 APR 8 PM 12 06

HISTORICAL DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year____	Year___	Year_____
1.	$_____	$_____	$_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
Total Other Expenses	$_____	$_____	$_____

PROJECTED DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year 1	Year 2
1. MRI service/maintenance contract ($9,000 mo)	$ 108,000	$ 108,000
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
Total Other Expenses	$ 108,000	$ 108,000

Approved January 25, 2012
Square feet: 450
Construction cost $405,000
Construction cost per square foot: $900

4. Complete Historical and Projected Data Charts on the following two pages--*Do not modify the Charts provided or submit Chart substitutions!* Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

The Historical Data Chart and the Projected Data Chart have been completed and are included as Attachment C Economic Feasibility 4.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

The project's average gross charge will be $1584.55 for MRI's, with the provision for contractual adjustments, charity and bad debt averaging $691.89 per scan, the average net charge then becomes $892.66.

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

As the proposal involves a new service (MRI), there are no current charge schedules and no projected adjustment to current charges. The average projected gross charge, average projected deduction (including projected contractual adjustments, provision for charity care and bad debts), the average projected net charge, and the anticipated revenue from the proposed project for the two years following completion are presented in the table below as well as in the Projected Data Chart.

	Year 1	Year 2
Average Gross Charge	$1584.55	$1584.55
Average Projected Deduction	$691.89	$691.89
Average Projected Net Charge	$892.66	$892.66
Anticipated Gross Operating Revenue	$4,367,020	$4,585,688
Anticipated Net Operating Revenue	$2,460,171	$2,583,358

B. Compare the proposed charges to those of similar facilities in the service

Washington	Appalachian Orthopaedic Associates –Johnson City	$1,063.86
Washington	Franklin Woods Community Hospital*	$3,810.86*
Washington	Johnson City Medical Center*	$3,853.59*
Washington	Mountain States Imaging at Med Tech Parkway*	$3,718.22*
Washington	Watauga Orthopaedics, PLC	$1,410.16
AVERAGE GROSS CHARGE PER PROCEDURE – ALL facilities		$2,700.78
AVERAGE GROSS CHARGE PER PROCEDURE – owned by Mountain States Health Alliance		$3,773.12
AVERAGE GROSS CHARGE PER PROCEDURE – NOT owned by Mountain States Health Alliance		$1,959.99
% increase in average gross charge		92.51%
**and shading indicates ownership by Mountain States Health Alliance*		

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Projected utilization is based on current utilization rates of MRI services of Medical Care, PLLC patients and the historic rate of growth in patients at the medical practice. The Projected Data Chart outlines the cost-effectiveness of the proposal. A positive cash flow is expected in the first year of operation.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Revenue and expense information for this proposal for Years 1 and 2 following project completion is included in the Projected Data Chart. The net operating income less capital expenditures as represented is projected to be $773,783 in year 1 and $807,140 in year 2.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Medical Care, PLLC is both a TennCare and Medicare provider. In the previous year, during the period November 20, 2011 to November 20, 2012, 31.24% of the patients treated at Medical Care, PLLC were TennCare enrollees. During the same period, 9.49% of the patients were on Medicare. Private insurance accounted for 38.55% of the patients, Worker's Compensation accounted for 5.36% of the patients and private pay accounted for 14.71% of the patients. Medical Care, PLLC anticipates seeing a similar payor mix in the future.

The estimated dollar amount of revenue and percentage of total project revenue anticipated from TennCare and Medicare for the proposals first year of operation is set forth below (note that Medical Care, PLLC typically sees TennCare and Medicare patients more frequently than other patient populations because they tend to have more chronic conditions. Accordingly, the percentage of anticipated revenue from TennCare and Medicare reflected below is higher than the percentage of patients noted above. The percentage of anticipated revenue is based on the medical practice's current percentage of TennCare/Medicare revenue for patient visits.):

SUPPLEMENTAL- # 2
April 8, 2013
12:05 pm

AFFIDAVIT
2013 APR 8 PM 12 06

STATE OF TENNESSEE

COUNTY OF Carter

NAME OF FACILITY: Medical Care PLLC

I, Arnold Hoagland, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 4th day of April, 2013, witness my hand at office in the County of Carter, State of Tennessee.

NOTARY PUBLIC

My commission expires 08-19-2014.

HF-0043

Revised 7/02